

Historic, archived document

Do not assume content reflects current scientific knowledge, policies, or practices.

LEGISLATIVE HISTORY

Public Law 85-929
H. R. 13254

TABLE OF CONTENTS

Index and Summary of H. R. 13254.....	1
Digest of Public Law 85-929.....	2

Index and Summary of H. R. 13254

- July 1, 1958 Rep. Williams introduced H. R. 13254 which was referred to the House Interstate and Foreign Commerce Committee. Print of bill.
- July 25, 1958 House committee ordered H. R. 13254 reported.
- July 28, 1958 House subcommittee reported H. R. 13254 with amendment. H. Rept. No. 2284. Print of bill and report.
- Aug. 13, 1958 House passed H. R. 13254 under suspension of rules.
- Aug. 14, 1958 H. R. 13254 was referred to Senate Labor and Public Welfare Committee. Print of bill as referred.
- Aug. 15, 1958 Senate committee ordered H. R. 13254 reported with amendments.
- Aug. 18, 1958 Senate committee reported H. R. 13254 with amendments. S. Rept. 2422. Print of bill and report.
- Aug. 20, 1958 Senate passed over H. R. 13254
- Aug. 23, 1958 Senate passed H. R. 13254 with amendments. House concurred in Senate amendments.
- Sept. 6, 1958 Approved: Public Law 85-929

HEARINGS: Before a subcommittee of the House Interstate and Foreign Commerce Committee July and August 1957; April 1958.

DIGEST OF PUBLIC LAW 85-929

Public Law 85-929 (H. R. 13254) FOOD ADDITIVES AMENDMENT OF 1958 (Approved September 6, 1958). Amends the Federal Food, Drug and Cosmetic Act so as to require manufacturers of food additives and food processors to ~~pro~~^{o-}test any potentially unsafe substances which are to be added to food. Authorizes the Secretary of Health, Education, and Welfare to exempt food additives for investigational use by qualified experts when consistent with the public health. Prescribes procedures for regulating the use of food additives. Provides that the term "food additive," as used in this act, does not include a pesticide chemical in or on a raw agricultural commodity, or which is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity, or any substance used in accordance with the Poultry Products Inspection Act or the Meat Inspection Act.

85TH CONGRESS
2D SESSION

H. R. 13254

IN THE HOUSE OF REPRESENTATIVES

JULY 1, 1958

Mr. WILLIAMS of Mississippi introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Food Additives Amend-
4 ment of 1958".

5 SEC. 2. Section 201, as amended, of the Federal Food,
6 Drug, and Cosmetic Act is further amended by adding at
7 the end of such section the following new paragraphs:

8 “(s) The term ‘food additive’ means any substance the
9 intended use of which results or may reasonably be expected

1 to result, directly or indirectly, in its becoming a component
2 or otherwise affecting the characteristics of any food (includ-
3 ing any substance intended for use in producing, manufac-
4 turing, packing, processing, preparing, treating, packaging,
5 transporting, or holding food; and including any source of
6 ionizing radiation intended for any such use, if such substance
7 is not generally recognized, among experts qualified by scien-
8 tific training and experience to evaluate its toxicity or other
9 potentiality for harm, as having been adequately shown
10 through scientific procedures (or, in the case of a substance
11 used in food prior to the date of enactment of this paragraph,
12 through either scientific procedures or experience based on
13 common use in food) to be safe under the conditions of its
14 intended use; except that such term does not include—

15 “(1) a pesticide chemical in or on a raw agricultural
16 commodity; or

17 “(2) a pesticide chemical to the extent that it is
18 intended for use in the production, storage, or trans-
19 portation of any raw agricultural commodity; or

20 “(3) any substance used in accordance with a sanc-
21 tion or approval granted prior to the enactment of this
22 paragraph pursuant to this Act or the Meat Inspection
23 Act of March 4, 1907 (34 Stat. 1260), as amended and
24 extended (21 U. S. C. 71 and the following).

25 “(t) The term ‘safe’, as used in paragraph (s) of this

1 section and in section 409, means without hazard to the
2 health of man or animal.”

3 SEC. 3. (a) Clause (2) of section 402 (a), as amended,
4 of such Act is amended to read as follows: “(2) (A) if it
5 bears or contains any added poisonous or added deleterious
6 substance (except a pesticide chemical in or on a raw agri-
7 cultural commodity and except food additive) which is un-
8 safe within the meaning of section 406, or (B) if it is a
9 raw agricultural commodity and it bears or contains a pesti-
10 cide chemical which is unsafe within the meaning of section
11 408 (a), or (C) if it is, or it bears or contains, any food
12 additive which is unsafe within the meaning of section 409:
13 *Provided*, That where a pesticide chemical has been used in
14 or on a raw agricultural commodity in conformity with an
15 exemption granted or a tolerance prescribed under section
16 408 and such raw agricultural commodity has been subjected
17 to processing by cooking, freezing, dehydrating, or milling,
18 the residue of such pesticide chemical remaining in or on
19 such processed food shall, notwithstanding the provisions of
20 sections 406 and 409, not be deemed unsafe if such residue
21 in or on the raw agricultural commodity has been removed
22 to the extent possible in good manufacturing practice and
23 the concentration of such residue in the processed food when
24 ready to eat is not greater than the tolerance prescribed for
25 the raw agricultural commodity;”.

1 (b) Section 402 (a) , as amended, of such Act is further
2 amended by striking out the period at the end thereof and
3 inserting in lieu thereof a semicolon and the following: “or
4 (7) if it has been intentionally subjected to ionizing radiation,
5 unless the use of the ionizing radiation was in conformity
6 with a regulation or exemption in effect pursuant to section
7 409.”

8 (c) The first sentence of section 406 (a) of such
9 Act is amended by striking out “clause (2)” wherever it
10 appears in such sentence and inserting in lieu thereof “clause
11 (2) (A)”.

12 SEC. 4. Chapter IV of such Act is amended by adding
13 at the end thereof the following new section:

14 “FOOD ADDITIVES

15 “Unsafe Food Additives

16 “SEC. 409. (a) A food additive shall, with respect to
17 any particular use or intended use of such additives, be
18 deemed to be unsafe for the purposes of the application
19 of clause (2) (C) of section 402 (a) , unless—

20 “(1) it and its use or intended use conform to the
21 terms of an exemption which is in effect pursuant to sub-
22 section (j) of this section; or

23 “(2) there is in effect, and it and its use or
24 intended use are in conformity with, a regulation issued

1 under this section prescribing the conditions under
2 which such additive may be safely used.

3 While such a regulation relating to a food additive is in
4 effect, a food shall not, by reason of bearing or containing
5 such an additive in accordance with the regulation, be con-
6 sidered adulterated within the meaning of clause (1) of sec-
7 tion 402 (a).

8 "Petition To Establish Safety

9 "(b) (1) Any person may, with respect to any in-
10 tended use of a food additive, file with the Secretary a
11 petition proposing the issuance of a regulation prescribing
12 the conditions under which such additive may be safely used.

13 "(2) Such petition shall, in addition to stating reason-
14 able grounds in support of the petition, contain—

15 "(A) the name and all pertinent information con-
16 cerning such food additive, including, where available,
17 its chemical identity and composition;

18 "(B) a statement of the conditions of the pro-
19 posed use of such additive, including all directions,
20 recommendations, and suggestions proposed for the use
21 of such additive, and including specimens of its proposed
22 labeling;

23 "(C) all relevant data bearing on the physical or
24 other technical effect such additive is intended to pro-

1 duce, and the quantity of such additive required to
2 produce such effect;

3 “(D) a full description of the methods used in,
4 and the facilities and controls used for, the production
5 of such additive;

6 “(E) a description of practicable methods for de-
7 termining the quantity of such additive in or on food,
8 and any substance formed in or on food, because of
9 its use; and

10 “(F) full reports of investigations made with re-
11 spect to the toxicity or other potentiality for harm of
12 such additive, including full information as to the
13 methods and controls used in conducting such investi-
14 gations.

15 “(3) Upon request of the Secretary, the petitioner shall
16 furnish samples of the food additive involved, or articles
17 used as components thereof, and of the food in or on which
18 the additive is proposed to be used.

19 “(4) Notice of the regulation proposed by the petitioner
20 shall be published in general terms by the Secretary within
21 thirty days after filing.

22 “Action on the Petition

23 “(c) (1) The Secretary shall, in the absence of a refer-
24 ral, or request for referral, to an advisory committee made
25 pursuant to subsection (e) of this section—

“(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use, and shall notify the petitioner of such order; or

“(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

“(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

1 “(3) No such regulation shall issue if the data before
2 the Secretary—

3 “(A) fail to establish that the proposed use of the
4 food additive, under the conditions of use to be specified
5 in the regulation, will be safe; or

6 “(B) show that the proposed use of the additive
7 would promote deception of the consumer or would be
8 otherwise contrary to this Act.

9 “(4) If, in the judgment of the Secretary, a tolerance
10 limitation is required in order to assure that the proposed use
11 of an additive will be safe, the Secretary—

12 “(A) shall not fix such tolerance limitation at a
13 level higher than he finds to be reasonably required to
14 accomplish the physical or other technical effect for
15 which such additive is intended; and

16 “(B) shall not establish a regulation for such pro-
17 posed use if he finds that the data before him do not
18 establish that such use would accomplish the intended
19 physical or other technical effect.

20 “(5) In determining, for the purposes of this section,
21 whether a proposed use of a food additive is safe, the Sec-
22 retary shall consider among other relevant factors—

23 “(A) the probable consumption of the additive
24 and of any substance formed in or on food because of
25 the use of the additive;

1 “(B) the cumulative effect of such additive in the
2 diet of man or animals, taking into account any chemi-
3 cally or pharmacologically related substance or substances
4 in such diet; and

5 “(C) appropriate safety factors for the use of
6 animal experimentation data.

7 “Regulation Issued on Secretary's Initiative

8 “(d) The Secretary may at any time, upon his own
9 initiative, propose the issuance of a regulation prescribing,
10 with respect to any particular use of a food additive, the
11 conditions under which such additive may be safely used.
12 After the thirtieth day following publication of such a pro-
13 posal, the Secretary may by order establish a regulation
14 based upon the proposal, unless within such thirty-day period
15 a person files a petition under subsection (b) with respect
16 to such additive and requests that the proposal, or any
17 question of fact raised thereby, be referred to an advisory
18 committee appointed pursuant to subsection (e) of this
19 section.

20 “Reference to Advisory Committee

21 “(e) (1) At any time before, or within thirty days
22 after, publication of an order issued under subsection (c)
23 or (d) of this section, the petitioner may request that the
24 petition or order thereon, or the Secretary's proposal, or

1 any question raised by such petition, order, or proposal, be
2 referred to an advisory committee. Upon such request, or
3 if the Secretary within such time deems such a referral
4 necessary, the Secretary shall forthwith appoint an advisory
5 committee of competent experts to review the petition,
6 order, or proposal, or question, as the case may be, and to
7 make a report and recommendation thereon. Each such
8 advisory committee shall be composed of experts, qualified
9 in the subject matter of the petition, order, proposal, or
10 question, as the case may be, and of adequately diversified
11 professional background selected by the National Academy
12 of Sciences, except that in the event of the inability or
13 refusal of the National Academy of Sciences to act, the
14 Secretary shall select the members of the committee. The
15 size of the committee shall be determined by the Secretary.
16 Members of an advisory committee shall receive as com-
17 pensation for their services a reasonable per diem, which
18 the Secretary shall by rules and regulations prescribe, for
19 time actually spent in the work of the committee, and shall
20 in addition be reimbursed for their necessary traveling and
21 subsistence expenses while so serving away from their places
22 of residence. The members shall not be subject to any other
23 provisions of law regarding the appointment and compen-
24 sation of employees of the United States. The Secretary
25 shall furnish the committee with adequate clerical and other

1 assistance, and shall by rules and regulations prescribe the
2 procedure to be followed by the committee. The Secretary
3 shall refer the petition, order, or proposal, or question, as
4 the case may be, to the advisory committee so appointed,
5 and furnish such committee all the data before him. A
6 person who has filed a petition or who has requested the
7 referral of an order, proposal, or question, to an advisory
8 committee, as well as representatives of the Department of
9 Health, Education, and Welfare, shall have the right to
10 consult with such advisory committee in connection with the
11 matter referred to it."

12 " (2) Within sixty days after the date of such referral,
13 or within an additional thirty days if the committee deems
14 such additional time necessary, the committee shall, after
15 independent study of the data furnished to it by the Sec-
16 retary and other data before it, certify to the Secretary a
17 report and recommendations, together with all underlying
18 data and a statement of the reasons or basis for the recom-
19 mendations. Within thirty days after such certification,
20 and after giving due consideration to all data then before
21 him, including such report, recommendations, underlying
22 data, and statement, and to any prior order issued by him
23 in connection with such matter, the Secretary shall confirm
24 or modify any order theretofore issued or, if no such order
25 has been issued, shall by order establish a regulation pre-

1 scribing, with respect to any particular use of the food
2 additive involved, the conditions under which such additive
3 may be safely used or shall, by order, deny the petition.

4 “(3) The Secretary may by regulation condition re-
5 ferrals to advisory committees pursuant to this subsection
6 upon the payment, by the person requesting the referral, of
7 fees to defray the costs arising by reason of such referrals.
8 Such fees, including advance deposits to cover such fees, shall
9 be available, until expended, for paying (directly or by way
10 of reimbursement of the applicable appropriation) the ex-
11 penses of advisory committees under this subsection and other
12 expenses arising by reason of referrals to such committees,
13 and for refunds of excess payments.

14 “Publication and Effective Date of Orders

15 “(f) Any order, including any regulation established
16 by such order, issued under subsection (c), (d), or (e) of
17 this section, shall be published and shall be effective upon
18 publication, but the Secretary may stay such effectiveness
19 if, after issuance of such order, the order or any question
20 related thereto is referred to an advisory committee pursu-
21 ant to subsection (e) or if a hearing is sought with respect
22 to such order pursuant to subsection (g).

23 “Objections and Public Hearing

24 “(g) (1) Within thirty days after publication of an
25 order made pursuant to subsection (c), (d), or (e) of this

1 section, any person adversely affected by such an order may
2 file objections thereto with the Secretary, specifying with
3 particularity the provisions of the order deemed objection-
4 able, stating reasonable grounds therefor, and requesting a
5 public hearing upon such objections. The Secretary shall
6 thereupon, after due notice, hold such public hearing for the
7 purpose of receiving evidence relevant and material to the
8 issues raised by such objections. Any report, recommenda-
9 tions, underlying data, and reasons certified to the Secretary
10 by an advisory committee shall be made a part of the record
11 of the hearing if relevant and material, subject to the provi-
12 sions of section 7 (c) of the Administrative Procedure Act
13 (5 U. S. C., sec. 1006 (c)). The advisory committee shall
14 designate a member to appear and testify at any such hear-
15 ing with respect to the report and recommendations of such
16 committee upon request of the Secretary, the petitioner, or
17 the officer conducting the hearing, but this shall not preclude
18 any other member of the advisory committee from appearing
19 and testifying at such hearing. As soon as practicable after
20 completion of the hearing, the Secretary shall by order act
21 upon such objections and make such order public.

22 “(2) Such order shall be based upon a fair evaluation
23 of the entire record at such hearing, including any report,
24 recommendations, underlying data, and reasons certified to
25 the Secretary by an advisory committee, and shall include a

1 statement setting forth in detail the findings and conclusions
2 upon which the order is based.

3 “(3) The Secretary shall specify in the order the date
4 on which it shall take effect, except that it shall not be
5 made to take effect prior to the ninetieth day after its
6 publication, unless the Secretary finds that emergency con-
7 ditions exist necessitating an earlier effective date, in which
8 event the Secretary shall specify in the order his findings as
9 to such conditions.

10 “Judicial Review

11 “(h) (1) In a case of actual controversy as to the
12 validity of any order issued under subsection (g), including
13 any order thereunder with respect to amendment or repeal of
14 a regulation issued under this section, any person who will
15 be adversely affected by such order may obtain judicial
16 review by filing in the United States Court of Appeals for
17 the circuit wherein such person resides or has his principal
18 place of business, or in the United States Court of Appeals
19 for the District of Columbia Circuit, within sixty days after
20 the entry of such order, a petition praying that the order
21 be set aside in whole or in part.

22 “(2) A copy of such petition shall be forthwith served
23 upon the Secretary, or upon any officer designated by him
24 for that purpose, and thereupon the Secretary shall certify
25 and file in the court a transcript of the proceedings and the

1 record on which he based his order. Upon such filing, the
2 court shall have exclusive jurisdiction to affirm or set aside
3 the order complained of in whole or in part. The findings
4 of the Secretary with respect to questions of fact shall be
5 sustained if based upon a fair evaluation of the entire record
6 at such hearing, including any report, recommendation,
7 underlying data, and reasons certified to the Secretary by an
8 advisory committee.

9 “(3) If application is made to the court for leave to
10 adduce additional evidence, the court may order such addi-
11 tional evidence to be taken before the Secretary and to be
12 adduced upon the hearing in such manner and upon such
13 terms and conditions as to the court may seem proper, if
14 such evidence is material and there were reasonable grounds
15 for failure to adduce such evidence in the proceedings below.
16 The Secretary may modify his findings as to the facts and
17 order by reason of the additional evidence so taken, and
18 shall file with the court such modified findings and order.

19 “(4) The judgment of the court affirming or setting
20 aside, in whole or in part, any order under this section shall
21 be final, subject to review by the Supreme Court of the
22 United States upon certiorari or certification as provided
23 in section 1254 of title 28 of the United States Code. The
24 commencement of proceedings under this section shall not,
25 unless specifically ordered by the court to the contrary,

1 operate as a stay of an order. The court shall advance on
2 the docket and expedite the disposition of all causes filed
3 therein pursuant to this section.

4 “(5) The court, on such judicial review, shall not sustain
5 the order of the Secretary if he failed to comply with any
6 requirement imposed on him by subsection (g) (2) of this
7 section.

8 “Amendment or Repeal of Regulations

9 “(i) The Secretary shall by regulation prescribe the
10 procedure by which regulations under the foregoing pro-
11 visions of this section may be amended or repealed, and
12 such procedure shall conform to the procedure provided
13 in this section for the promulgation of such regulations, in-
14 cluding the appointment of advisory committees and the
15 procedure for referring matters to such committees.

16 “Exemptions for Investigational Use

17 “(j) Without regard to subsections (b) to (i), inclu-
18 sive, of this section, the Secretary shall by regulation provide
19 for exempting from the requirements of this section any
20 food additive, and any food bearing or containing such addi-
21 tive, intended solely for investigational use by qualified ex-
22 perts when in his opinion such exemption is consistent with
23 the public health.”

24 SEC. 5. Section 301 (j) of such Act is amended by
25 inserting “409” after “404,”.

1 SEC. 6. (a) Except as provided in subsections (b) and
2 (c) of this section, this Act shall take effect on the date of
3 its enactment.

4 (b) Except as provided in subsection (c) of this section,
5 section 3 of this Act shall take effect on the one hundred and
6 eightieth day after the date of enactment of this Act.

7 (c) With respect to any particular commercial use of a
8 food additive, if such use was made of such additive before
9 January 1, 1958, section 3 of this Act shall take effect—

10 (1) either (A) one year after the effective date
11 established in subsection (b) of this section, or (B) at
12 the end of such additional period (but not later than
13 two years from such effective date established in sub-
14 section (b)) as the Secretary of Health, Education, and
15 Welfare may prescribe on the basis of a finding that
16 such extension involves no undue risk to the public
17 health and that conditions exist which necessitate the
18 prescribing of such an additional period, or

19 (2) on the date on which an order with respect to
20 such use under section 409 of the Federal Food, Drug,
21 and Cosmetic Act becomes effective,
22 whichever date first occurs.

23 SEC. 7. Nothing in this Act shall be construed to ex-
24 empt any meat or meat food product or any person from

1 any requirement imposed by or pursuant to the Meat Inspec-
2 tion Act of March 4, 1907, 34 Stat. 1260, as amended and
3 extended (21 U. S. C. 71 and the following) .

85TH CONGRESS
2D SESSION

H. R. 13254

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

By Mr. WILLIAMS of Mississippi

JULY 1, 1958

Referred to the Committee on Interstate and Foreign
Commerce

July 25, 1958

livestock. He also stated that there would be a call of the calendar Monday, July 28. p. 13861.

6. ADJOURNED until Mon., July 28. p. 13880

HOUSE

7. AGRICULTURE COMMITTEE ordered reported the following bills:

- H. R. 11056, to amend the Agricultural Marketing Agreement Act so as to extend restrictions on certain imported citrus fruits, dried fruits, and nuts;
- H. R. 13268, to authorize CCC to purchase flour and cornmeal for donation instead of having such products processed from its own stocks;
- S. 479, to grant a 50-year right-of-way for a water pipeline across the Lincoln National Forest, N. M.;
- S. 1245, to provide a right-of-way to the city of Alamogordo, N. M., across the Lincoln National Forest, N. M.; and
- S. 3439, to reconvey to Salt Lake City the Forest Service Fire Warehouse lot in that city. p. D736

8. WATERSHED PROJECTS. The Agriculture Committee approved the following watershed projects: Mill Creek, Ga.; Obion Creek, Ky.; Muddy Creek, Miss. and Tenn.; Adobe Creek, Calif.; Buena Vista Creek, Calif.; Central Sonoma Creek, Calif.; Upper Nanticoke River, Ill.; Donaldson Creek, Ky.; Mud Creek, Neb.; Coon Creek, Wis.; Peavine Mountain Creek, Nev.; and Indian Creek, Miss. p. D737

9. FORESTRY. The Interior and Insular Affairs Committee reported with amendment S. 3051, to provide for either private or Federal acquisition of that part of the Klamath Indian Forest which must be sold (H. Rept. 2278). p. 13897

10. FOOD ADDITIVES. The Interstate and Foreign Commerce Committee ordered reported H. R. 13254, to prohibit the use of food additives which have not been adequately tested to establish their safety. p. D738

11. LEGISLATIVE PROGRAM. Rep. McCormack announced that on Tues., July 29, the House will consider S. 3051, the Klamath forest bill, and S. 3817, to encourage mining through direct payments to producers; and that on Wed., July 30, the only programmed bill will be H. R. 9020, to amend the Packers and Stockyards Act to transfer jurisdiction over certain transactions from USDA to FTC, but that other bills might be taken up if rules could be secured from the Rules Committee, including housing, distressed areas redevelopment, and community facilities bills. pp. 13887-8

12. ADJOURNED until Mon., July 28. p. 13891

ITEMS IN APPENDIX

13. ETHICS. Rep. Bennett inserted the code of ethics for Government service adopted as the intent of Congress on July 11, and also inserted the report of the Senate committee on the measure. pp. A6705-7

14. FOREIGN AID. Sen. Jenner inserted an editorial criticizing the expenditure of mutual security funds in the Near East and South Asia in the last 10 years as a failure. p. A6696

15. FORESTRY. Sen. Dworshak inserted an editorial criticizing^{ing} the proposed wilderness bill as an attempt to freeze Idaho's progress by preventing the development of wilderness areas. p. A6697
Rep. Avery inserted an editorial commending the Outdoor Recreation Resource study authorized by Congress. p. A6701
Rep. Ullman inserted a column on the need for an inventory of our shrinking outdoor recreational facilities. p. A6710
16. FOOD ADDITIVES. Rep. Dingell inserted an editorial opposing enactment of H. R. 9521, to eliminate the present requirement for labeling fresh produce to indicate whether post-harvest chemicals are used. p. A6707

BILLS INTRODUCED

17. ACREAGE ALLOTMENT. S. 4189, by Sen. Capehart, to amend the Agricultural Adjustment Act of 1938, as amended, to provide for additional allotments when an allotment crop has been entirely lost or destroyed because of a natural disaster; to Agriculture and Forestry Committee. Remarks of author. p. 13737
18. POSTAL RATES. S. 4191, by Sen. Monroney, to maintain existing minimum postage rates on certain publications mailed in the county of publication; to Post Office and Civil Service Committee. Remarks of author. pp. 13737-8
19. SEED. S. 4188, by Sen. Magnuson (by request), and H. R. 13545, by Rep. Pelly, to amend the Federal Seed Act so as to permit the importation screenings of rape/^{seed} and mustard seed; to S. Agriculture and Forestry Committee and H. Agriculture Committee.
20. FLOOD CONTROL. S. 4192, by Sen. Sen. Johnson, Tex., authorizing the project for modification of the plan for improvement of the Trinity River and tributaries, Tex.; to Public Works Committee. Remarks of author. p. 13880

-0-

COMMITTEE HEARINGS ANNOUNCEMENTS:

July 28: Sale or exchange of forest land in Pima County, Ariz., S. Interior (Crafts, FS, to answer questions).
USDA supplemental appropriations, S. Appropriations.
H. Agriculture subcommittee on Cotton and Rice (exec).
Minerals stabilization payments, H. Interior.

o0o

For supplemental information or copies of legislative material referred to, call Ext. 4654 or send to Room 105-A.

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF BUDGET AND FINANCE
(For Department Staff Only)

Issued July 29, 1958
For actions of July 28, 1958
85th-2d, No. 127

CONTENTS

Budgeting.....	18,25,36		
Civil defense.....	5		
Economic situation.....	22		
Electrification.....	6,28		
Ethics.....	27		
Farm labor.....	3		
Farm program.....	14		
Fish.....	21		
Flag.....	31,34		
Flood insurance.....	8	Minerals.....	2,1
Food additives.....	4,33	Monopolies.....	9,20
Foreign aid.....	10	Personnel.....	27
Foreign trade.....	23	Public debt.....	7
Forestry.....	1,26,38	Reclamation.....	15
Highways.....	19	Renegotiation Act.....	35
Legislative program..	12,24	Research.....	13
Libraries.....	32	River compact.....	16
		Small business.....	35
		Soil conservation.....	37
		Stabilization payments...	2
		Statehood.....	29
		Water, conservation.....	11
		pollution.....	30
		resources.....	17,21
		Wildlife.....	21

HIGHLIGHTS: Senate debated industrial uses research bill. Sen. Proxmire criticized farm bill. Rep. McGovern urged greater authority for REA administrator.

HOUSE

1. FORESTRY. The Interior and Insular Affairs Committee ordered reported S. 1748, with amendment, to add certain lands in Ida. and Wyo. to the Caribou and Targh National Forests, and S. 2517, to authorize the States to choose mineral lands in making selections in lieu of sections of public lands occupied before State claims were made. p. D745
2. MINERALS. The Interior and Insular Affairs Committee ordered reported S. 4036, to provide stabilization payments to certain minerals producers. p. D745
3. FARM LABOR. A subcommittee of the Agriculture Committee ordered reported on July 25, with amendment, H. R. 10360, to continue for 2 years the authority of the Attorney General to permit the importation of aliens for agricultural employment. p. D745
4. FOOD ADDITIVES. The Interstate and Foreign Commerce Committee reported with amendment H. R. 13254, to amend the Federal Food, Drug, and Cosmetic Act so as to prohibit the use in food and additives which have not been adequately tested to establish their safety (H. Rept. 2284). p. 14037

5. CIVIL DEFENSE. Concurred in the Senate amendments to H. R. 7576, to amend the Federal Civil Defense Act of 1950 so as to permit the expansion of the civil-defense activity of the Federal Government to assume more responsibility for the national program. This bill will now be sent to the President. p. 14023
6. ELECTRIFICATION. Rep. McGovern charged that partisan politics was entering into the administration of the REA program, criticized certain administration proposals regarding the financing of REA loans, and urged the enactment of legislation to grant greater administrative authority to the REA administrator. pp. 14030-32
7. PUBLIC DEBT. Both Houses received from the President a request to increase the regular statutory debt limit to \$285 billion, and to provide an additional temporary increase of \$3 billion through June 30, 1960 (H. Doc. 425). pp. 14019, 13905
8. FLOOD INSURANCE. Both Houses received from the President the final report of Housing and Home Finance Agency on the activities of the Federal Flood Indemnity Administration, which was abolished July 1, 1957 (H. Doc. 426). pp. 14015, 13889
9. MONOPOLIES. Rep. Patman inserted an article analyzing the provisions and urging the enactment of H. R. 11 and S. 11, to reaffirm and strengthen the national policy and purpose of Congress in the laws against unlawful restraints and monopolies. pp. 14034-36
10. FOREIGN AID. Both Houses received from GAO a report on the examination of the economic and technical assistance program for Turkey through June 30, 1957. pp. 14037, 13905
11. WATER CONSERVATION. Both Houses received from Interior a copy of an application for a loan of \$2,780,000 to the Roosevelt Water Conservation District in Ariz. pp. 14037, 13905
12. LEGISLATIVE PROGRAM. Rep. McCormack announced that S. 25, to specify the effective date upon which changes in pay of wage-board employees shall begin following the start of a survey, will be eligible for consideration under suspension of the rules today, July 29. p. 14015

SENATE

13. RESEARCH. Began debate on S. 4100, to provide for the increased use of agricultural products for industrial purposes. Adopted an amendment by Sen. Ellender to strike out the subsection authorizing the grant of rapid amortization certificates on the ground that this was a violation of the House's power to initiate tax bills (p. 13951). The committee amendments were adopted, and the Senate agreed to have a yea-and-nay vote on the bill immediately following the routine morning business today, July 29. pp. 13943, 13946-64, 14004, 14006-9, 14011.
14. FARM PROGRAM. Sen. Proxmire stated that the farmers in Wis. opposed and criticized passage of S. 4071, the Senate farm bill, and predicted that enactment of the bill would "cast a great blight on farmers all over the country." pp. 14006-7
15. RECLAMATION. Passed without amendment H. R. 8645, to amend the Reclamation Project Act to provide relief for individual reclamation projects through

FOOD ADDITIVES AMENDMENT OF 1958

JULY 28, 1958.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WILLIAMS of Mississippi, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H. R. 13254]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, having considered the same, report favorably thereon with an amendment and recommend that the bill, as amended, do pass.

The amendment is as follows:

The amendment strikes all of the text of the introduced bill and inserts in lieu thereof a substitute which appears in the reported bill in italic type.

PURPOSE OF LEGISLATION

The purpose of the legislation is twofold:

(1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production or cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of

these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofore voluntarily assumed.

Although there has been complete agreement as to the need for this legislation, there have been differences between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

HISTORY OF LEGISLATION

During the 81st Congress, a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics (better known as the Delaney committee, named after its chairman, Congressman James J. Delaney) was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in this respect. After extended hearings, the committee on June 30, 1952, filed a report (H. Rept. No. 2356, 82d Cong., 2d sess.) urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of the report were introduced by Congressman Delaney and referred to this committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, the committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

During the 85th Congress, the Subcommittee on Health and Science held 11 days of hearings on 9 bills.¹ The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee the scientific background with regard to the testing and evaluating of the safety of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of the hearings and after consideration of the various bills, the chairman of the subcommittee, Congressman John Bell Williams of Mississippi, introduced a clean bill (H. R. 13254) which was reported unanimously by the subcommittee to the full committee.

The full committee unanimously reported the bill with one amendment which strikes out all after the enacting clause and inserts in place of the introduced bill a substitute. The principal difference between the proposed committee amendment and the introduced bill is the elimination of the provisions in the introduced bill relating to scientific advisory committees. The remaining differences are the result of clerical, technical, and clarifying changes.

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (including a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food,

¹ H. R. 366 (O'Hara of Minnesota), H. R. 6747 (Harris), H. R. 7700 (Fulton), H. R. 7798 (Delaney), H. R. 7938 (Sullivan), H. R. 8390 (Harris), H. R. 8629 (Wolverton), H. R. 8112 (Miller), and H. R. 10404, (Williams of Mississippi).

Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Regulation to establish safety

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of a petition filed by any person (ordinarily the manufacturer of the additive) or on the Secretary's own initiative.

The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practical methods to determine the quantity of such additive left in or on food because of its use.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

Concept of safety

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that

it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the "safety" of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

Grounds for denial of petition

The Secretary would deny a petition to establish the safety of an additive if the data before the Secretary fail to establish that the proposed use of the additive under the specified conditions of use will be safe.

The Secretary could also deny a petition on the ground that the proposed use of the additive would promote deception of the consumer in violation of the Food and Drug Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Food and Drug Act.

Tolerance limitations

In the case of an additive which in the judgment of the Secretary based upon a fair evaluation of the data before him, requires a tolerance limitation in order to assure that the proposed use of such additive will be safe, the legislation establishes two standards:

(1) the Secretary may not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(2) the Secretary may not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

The phrase "physical or other technical effect" refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food. The question of whether an additive produces such effect (or how much of an additive is required for such effect) is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added "value" to the consumer of such food or enhances the marketability from a merchandising point of view.

Advisory committees

The committee has deleted the advisory committee procedure from the bill because there does not appear to be any need for this complicated mechanism for securing the views of scientists. The Department already has the privilege of making inquiry of competent outside scientists on technical matters.

Public hearings

Any person adversely affected by an order of the Secretary may file objections thereto and request a public hearing. At such hearings the Secretary would receive evidence relevant and material to the issues raised and would by order act upon such objections.

Judicial review

The committee has given long and careful thought to the problem of the scope of judicial review under this legislation. This problem was discussed exhaustively by several witnesses, including a Federal judge who testified on behalf of the Judicial Conference of the United States.

The committee feels that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possible equal or even greater substance.

In the course of the scientific panel hearings, the subcommittee was impressed with the wide range of scientific judgment factors which are involved in determining the safety of a food additive. Considering the eminent qualifications of all the scientists and experts who participated in these panel hearings, the scientific testimony of any one of the participants must be considered "substantial evidence." Nevertheless, any conclusions based solely on the scientific judgment of any one of the participants without taking account of contradictory scientific views expressed by other participants cannot be considered conclusions based upon a fair evaluation of the entire record.

Thus, under this legislation, the Secretary's findings of fact and orders based thereon must be based upon a fair evaluation of the entire record. The committee adopted the language "fair evaluation of the entire record" because it seemed to express most clearly the standard of judicial review of administrative findings of fact and orders based thereon which the committee feels should prevail.

The bill provides that the reviewing court shall not sustain the order of the Secretary if he failed to base such order upon a fair evaluation of the entire record at such hearing, or if he failed to include in such

order a statement setting forth in detail the findings and conclusions upon which the order is based. The court must sustain the findings of the Secretary with respect to questions of fact if based upon a fair evaluation of the entire record.

Judicial review of any order of the Secretary under this legislation may be obtained in the United States court of appeals for the circuit wherein appellant resides, or has his principal place of business, or in the United States Court of Appeals for the District of Columbia.

Effective date

This legislation will, except as hereinafter stated, take effect on the date on which it is enacted. Thus the Food and Drug Administration can immediately begin making determinations as to the safety of food additives.

However, since it will take a certain amount of time to make these determinations of safety, the provisions of section 3 of the legislation (which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment in interstate commerce of an additive, or food containing an additive, which has not been determined to be safe) will not take effect until 180 days after the enactment of this legislation.

A further exception is made in the case of any particular commercial use of a food additive if such use began before January 1, 1958. In the case of such use, section 3 would take effect either on the establishment of an order with respect to the safety of such use, or 18 months after the date of enactment of the legislation (unless extended by the Secretary for not more than an additional 12 months), whichever date occurs first.

Meat inspection

The bill as amended provides that nothing in this legislation shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907. This provision would leave unaffected the jurisdiction of the Department of Agriculture with respect to food additives in establishments which are subject to the Meat Inspection Act.

The report of the Secretary of Health, Education, and Welfare reads as follows:

THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE,
Washington, July 11, 1958.

HON. OREN HARRIS,

*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D. C.*

DEAR MR. HARRIS: We note with gratification that the Health and Science Subcommittee of your committee has reported favorably a chemical food additives bill based essentially on H. R. 6747. We appreciate your great interest in this bill.

The subcommittee revision is acceptable to this Department.

Because of the urgent public health need for legislation requiring adequate testing of additives before they are used in food, we hope your committee can give favorable consideration to the new bill, H. R. 13254, in time for it to be acted upon by this session of Congress.

In view of the urgency, this communication has not been submitted to the Bureau of the Budget for advice in accordance with the usual procedure on reports.

Sincerely yours,

M. B. FOLSOM, *Secretary*.

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

AN ACT To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the U. S. Department of Health, Education, and Welfare.

(d) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term "drug" means (1) articles recognized in the official, United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling con-

tained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is an "economic poison" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U. S. C., secs. 135-135k), as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) *The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of ionizing radiation intended for any such use, if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its toxicity or other potentiality for harm, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to the date of enactment of this paragraph, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—*

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use in the production, storage, or transportation of any raw agricultural commodity; or

(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

(t) *The term "safe", as used in paragraph (s) of this section and in section 409, means without hazard to the health of man or animal.*

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, 506, 507, or 604.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection.

* * * * *

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for

avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance, **[except]** (*except a pesticide chemical in or on a raw agricultural commodity, commodity and except food additive*) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section **[408 (a)]** 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing by cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;* or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) *if it has been intentionally subjected to ionizing radiation, unless the use of the ionizing radiation was in conformity with a regulation or exemption in effect pursuant to section 409.*

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of*

coloring citrus fruit: *Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination'), the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F. D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21, Code of Federal Regulations, part 9: *And provided further*, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

- (a) If its labeling is false or misleading in any particular.
- (b) If it is offered for sale under the name of another food.
- (c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.
- (d) If its container is so made, formed, or filled as to be misleading.
- (e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measures, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.
- (f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

EMERGENCY PERMIT CONTROL

SEC. 404. (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found

that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Any officer or employer duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) (A) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations³ limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) (A) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors⁴ which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.

COLORED OLEOMARGARINE

SEC. 407 (a). Colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced shall be subject in the same manner and to the same extent to the provisions of this Act as if it had been introduced in interstate commerce.

(b) No person shall sell, or offer for sale, colored oleomargarine or colored margarine unless—

- (1) such oleomargarine or margarine is packaged,
- (2) the net weight of the contents of any package sold in a retail establishment is one pound or less,
- (3) there appears on the label of the package (A) the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and (B) a full and accurate statement of all the ingredients contained in such oleomargarine or margarine, and
- (4) each part of the contents of the package is contained in a wrapper which bears the word "oleomargarine" or "margarine" in type or lettering not smaller than 20-point type.

The requirements of this subsection shall be in addition to and not in lieu of any of the other requirements of this Act.

(c) No person shall possess in a form ready for serving colored oleomargarine or colored margarine at a public eating place unless a notice that oleomargarine or margarine is served is displayed prominently and conspicuously in such place and in such manner as to render it likely to be read and understood by the ordinary individual being served in such eating place or is printed or is otherwise set forth on the menu in type or lettering not smaller than that normally used to designate the serving of other food items. No person shall serve colored oleomargarine or colored margarine at a public eating place, whether or not any charge is made therefor, unless (1) each separate serving bears or is accompanied by labeling identifying it as oleomargarine or margarine, or (2) each separate serving thereof is triangular in shape.

(d) Colored oleomargarine or colored margarine when served with meals at a public eating place shall at the time of such service be exempt from the labeling requirements of section 403 (except (a) and 403 (f)) if it complies with the requirements of subsection (b) of this section.

(e) For the purpose of this section colored oleomargarine or colored margarine is oleomargarine or margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent.

TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

SEC. 408. (a) Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 402 (a) unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Secretary of Health, Education, and Welfare under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Secretary under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 402 (a).

(b) The Secretary shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (1) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Secretary may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Secretary does not justify the establishment of a greater tolerance.

(c) The Secretary shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) (1) Any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Secretary of Health, Education, and Welfare, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of, such economic poison, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Secretary upon request. Notice of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (1) with respect to the pesticide chemical named in the petition, the Secretary of Health, Education, and Welfare shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes,

unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Secretary within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (1) with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Secretary of Health, Education, and Welfare within such period otherwise deems such referral necessary, the Secretary of Health, Education, and Welfare shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the petition to the Secretary, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e), may file objections thereto with the Secretary, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U. S. C., sec. 1006 (c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(e) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary

and other data before it, certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

(f) All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section.

(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

(i) (1) In a case of actual controversy as to the validity of any order under subsection (d) (5), (e), or (l) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty

days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d) (5) or (e), a copy of the petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (1), a copy of the petition shall be forthwith served upon the Secretary of Agriculture, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The courts shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406 (a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 701 (e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d) (1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Secretary may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Secretary shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

(m) The Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) The provisions of section 303 (c) of the Federal Food, Drug, and Cosmetic Act with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d) (5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i) (2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

FOOD ADDITIVES

Unsafe Food Additives

Sec. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (j) of this section or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

Petition To Establish Safety

(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to stating reasonable grounds in support of the petition, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a full description of the methods used in, and the facilities and controls used for, the production of such additive;

(E) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(F) full reports of investigations made with respect to the toxicity or other potentiality for harm of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(4) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Action on the Petition

(c) (1) The Secretary shall, in the absence of a referral, or request for referral, to an advisory committee made pursuant to subsection (e) of this section—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use, and shall notify the petitioner of such order; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if the data before the Secretary—

(A) fail to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe; or

(B) show that the proposed use of the additive would promote deception of the consumer or would be otherwise contrary to this Act.

(4) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds that the data before him do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) appropriate safety factors for the use of animal experimentation data.

Regulation Issued on Secretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal, unless within such thirty-day period a person files a petition under subsection (b) with respect to such additive and requests that the proposal, or any question of fact raised thereby, be referred to an advisory committee appointed pursuant to subsection (e) of this section.

Reference to Advisory Committee

(e) (1) At any time before, or within thirty days after, publication of an order issued under subsection (c) or (d) of this section, the petitioner may request that the petition or order thereon, or the Secretary's proposal, or any question raised by such petition, order, or proposal, be referred to an advisory committee. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee of competent experts to review the petition, order, or proposal, or question, as the case may be, and to make a report and recommendation thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition, order, proposal, or question, as the case may be, and of adequately diversified professional background selected by the National Academy of Sciences, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee.

The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee. The Secretary shall refer the petition, order, or proposal, or question, as the case may be, to the advisory committee so appointed, and furnish such committee all the data before him. A person who has filed a petition or who has requested the referral of an order, proposal, or question, to an advisory committee, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it.

"(2) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall confirm or modify any order theretofore issued or, if no such order has been issued, shall by order establish a regulation prescribing, with respect to any particular use of the food additive involved, the conditions under which such additive may be safely used or shall, by order, deny the petition.

(3) The Secretary may by regulation condition referrals to advisory committees pursuant to this subsection upon the payment, by the person requesting the referral, of fees to defray the costs arising by reason of such referrals. Such fees, including advance deposits to cover such fees, shall be available, until expended, for paying (directly or by way of reimbursement of the applicable appropriation) the expenses of advisory committees under this subsection and other expenses arising by reason of referrals to such committees, and for refunds of excess payments.

Publication and Effective Date of Orders

(f) Any order, including any regulation established by such order, issued under subsection (c), (d), or (e) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, the order or any question related thereto is referred to an advisory committee pursuant to subsection (e) or if a hearing is sought with respect to such order pursuant to subsection (g).

Objections and Public Hearing

(g) (1) Within thirty days after publication of an order made pursuant to subsection (c), (d), or (e) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying

with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing if relevant and material, subject to the provisions of section 7 (c) of the Administrative Procedure Act (5 U. S. C., sec. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial Review

(h) (1) In a case of actual controversy as to the validity of any order issued under subsection (g), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing, including any report, recommendation, underlying data, and reasons certified to the Secretary by an advisory committee.

(3) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his

findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(4) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(5) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (g) (2) of this section.

Amendment or Repeal of Regulations

(i) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations, including the appointment of advisory committees and the procedure for referring matters to such committees.

Exemptions for Investigational Use

(j) Without regard to subsections (b) to (i), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.



H. R. 13254

[Report No. 2284]

IN THE HOUSE OF REPRESENTATIVES

JULY 1, 1958

Mr. WILLIAMS of Mississippi introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

JULY 28, 1958

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the “Food Additives Amend-
4 ment of 1958”.—

5 ~~SEC. 2. Section 201, as amended, of the Federal Food,~~
6 ~~Drug, and Cosmetic Act is further amended by adding at~~
7 the end of such section the following new paragraphs:

8 “(s) The term ‘food additive’ means any substance the
9 intended use of which results or may reasonably be expected

1 to result, directly or indirectly, in its becoming a component
2 or otherwise affecting the characteristics of any food (includ-
3 ing any substance intended for use in producing, manufac-
4 turing, packing, processing, preparing, treating, packaging,
5 transporting, or holding food; and including any source of
6 ionizing radiation intended for any such use, if such substance
7 is not generally recognized, among experts qualified by scien-
8 tific training and experience to evaluate its toxicity or other
9 potentiality for harm, as having been adequately shown
10 through scientific procedures (or, in the case of a substance
11 used in food prior to the date of enactment of this paragraph,
12 through either scientific procedures or experience based on
13 common use in food) to be safe under the conditions of its
14 intended use; except that such term does not include—

15 “(1) a pesticide chemical in or on a raw agricultural
16 commodity; or

17 “(2) a pesticide chemical to the extent that it is
18 intended for use in the production, storage, or trans-
19 portation of any raw agricultural commodity; or

20 “(3) any substance used in accordance with a sanc-
21 tion or approval granted prior to the enactment of this
22 paragraph pursuant to this Act or the Meat Inspection
23 Act of March 4, 1907 (34 Stat. 1260), as amended and
24 extended (21 U. S. C. 71 and the following).

25 “(t) The term ‘safe’, as used in paragraph (s) of this

1 section and in section 409, means without hazard to the
2 health of man or animal.”

3 SEC. 3. ~~(a)~~ Clause ~~(2)~~ of section 402 ~~(a)~~, as amended,
4 of such Act is amended to read as follows: “~~(2)~~ ~~(A)~~ if it
5 bears or contains any added poisonous or added deleterious
6 substance ~~(except a pesticide chemical in or on a raw agri-~~
7 ~~cultural commodity and except food additive)~~ which is un-
8 safe within the meaning of section 406; or ~~(B)~~ if it is a
9 raw agricultural commodity and it bears or contains a pesti-
10 cide chemical which is unsafe within the meaning of section
11 ~~408 (a)~~, or ~~(C)~~ if it is, or it bears or contains, any food
12 additive which is unsafe within the meaning of section 409:
13 *Provided*, That where a pesticide chemical has been used in
14 or on a raw agricultural commodity in conformity with an
15 exemption granted or a tolerance prescribed under section
16 408 and such raw agricultural commodity has been subjected
17 to processing by cooking, freezing, dehydrating, or milling,
18 the residue of such pesticide chemical remaining in or on
19 such processed food shall, notwithstanding the provisions of
20 sections 406 and 409, not be deemed unsafe if such residue
21 in or on the raw agricultural commodity has been removed
22 to the extent possible in good manufacturing practice and
23 the concentration of such residue in the processed food when
24 ready to eat is not greater than the tolerance prescribed for
25 the raw agricultural commodity;”

1 ~~(b)~~ Section 402 ~~(a)~~, as amended, of such Act is further
 2 amended by striking out the period at the end thereof and
 3 inserting in lieu thereof a semicolon and the following: “or
 4 ~~(7)~~ if it has been intentionally subjected to ionizing radiation;
 5 unless the use of the ionizing radiation was in conformity
 6 with a regulation or exemption in effect pursuant to section
 7 409.”

8 ~~(c)~~ The first sentence of section 406 ~~(a)~~ of such
 9 Act is amended by striking out “~~clause (2)~~” wherever it
 10 appears in such sentence and inserting in lieu thereof “~~clause~~
 11 ~~(2)~~ ~~(A)~~”.

12 SEC. 4. Chapter IV of such Act is amended by adding
 13 at the end thereof the following new section:

14 “FOOD ADDITIVES

15 “Unsafe Food Additives

16 “SEC. 409. ~~(a)~~ A food additive shall, with respect to
 17 any particular use or intended use of such additives, be
 18 deemed to be unsafe for the purposes of the application
 19 of ~~clause (2)~~ ~~(C)~~ of section 402 ~~(a)~~, unless—

20 “~~(1)~~ it and its use or intended use conform to the
 21 terms of an exemption which is in effect pursuant to sub-
 22 section ~~(j)~~ of this section; or

23 “~~(2)~~ there is in effect, and it and its use or
 24 intended use are in conformity with, a regulation issued

under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

Petition To Establish Safety

~~“(b) (1)~~ Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

~~“(2)~~ Such petition shall, in addition to stating reasonable grounds in support of the petition, contain—

~~“(A)~~ the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

~~“(B)~~ a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

~~“(C)~~ all relevant data bearing on the physical or other technical effect such additive is intended to pro-

1 duce, and the quantity of such additive required to
2 produce such effect;

3 “(D) a full description of the methods used in,
4 and the facilities and controls used for, the production
5 of such additive;

6 “(E) a description of practicable methods for de-
7 termining the quantity of such additive in or on food,
8 and any substance formed in or on food, because of
9 its use; and

10 “(F) full reports of investigations made with re-
11 spect to the toxicity or other potentiality for harm of
12 such additive, including full information as to the
13 methods and controls used in conducting such investi-
14 gations.

15 “(3) Upon request of the Secretary, the petitioner shall
16 furnish samples of the food additive involved, or articles
17 used as components thereof, and of the food in or on which
18 the additive is proposed to be used.

19 “(4) Notice of the regulation proposed by the petitioner
20 shall be published in general terms by the Secretary within
21 thirty days after filing.

22 “Action on the Petition

23 “(e) (1) The Secretary shall, in the absence of a refer-
24 ral, or request for referral, to an advisory committee made
25 pursuant to subsection (c) of this section—

1 ~~“(A) by order establish a regulation (whether~~
2 ~~or not in accord with that proposed by the petitioner)~~
3 ~~prescribing, with respect to one or more proposed uses~~
4 ~~of the food additive involved, the conditions under~~
5 ~~which such additive may be safely used (including, but~~
6 ~~not limited to, specifications as to the particular food or~~
7 ~~classes of food in or on which such additive may be~~
8 ~~used, the maximum quantity which may be used or per-~~
9 ~~mitted to remain in or on such food, the manner in~~
10 ~~which such additive may be added to or used in or on~~
11 ~~such food, and any directions or other labeling or~~
12 ~~packaging requirements for such additive deemed~~
13 ~~necessary by him to assure the safety of such use, and~~
14 ~~shall notify the petitioner of such order; or~~

15 ~~“(B) by order deny the petition, and shall notify~~
16 ~~the petitioner of such order and of the reasons for such~~
17 ~~action.~~

18 ~~“(2) The order required by paragraph (1) (A), or~~
19 ~~(B) of this subsection shall be issued within ninety days~~
20 ~~after the date of filing of the petition, except that the Secre-~~
21 ~~tary may (prior to such ninetieth day), by written notice~~
22 ~~to the petitioner, extend such ninety-day period to such~~
23 ~~time (not more than one hundred and eighty days after the~~
24 ~~date of filing of the petition) as the Secretary deems neces-~~
25 ~~sary to enable him to study and investigate the petition.~~

1 ~~“(3)~~ No such regulation shall issue if the data before
2 the Secretary—

3 ~~“(A)~~ fail to establish that the proposed use of the
4 food additive, under the conditions of use to be specified
5 in the regulation, will be safe; or

6 ~~“(B)~~ show that the proposed use of the additive
7 would promote deception of the consumer or would be
8 otherwise contrary to this Act.

9 ~~“(4)~~ If, in the judgment of the Secretary, a tolerance
10 limitation is required in order to assure that the proposed use
11 of an additive will be safe, the Secretary—

12 ~~“(A)~~ shall not fix such tolerance limitation at a
13 level higher than he finds to be reasonably required to
14 accomplish the physical or other technical effect for
15 which such additive is intended; and

16 ~~“(B)~~ shall not establish a regulation for such pro-
17 posed use if he finds that the data before him do not
18 establish that such use would accomplish the intended
19 physical or other technical effect.

20 ~~“(5)~~ In determining, for the purposes of this section,
21 whether a proposed use of a food additive is safe, the Sec-
22 retary shall consider among other relevant factors—

23 ~~“(A)~~ the probable consumption of the additive
24 and of any substance formed in or on food because of
25 the use of the additive;

1 “(B) the cumulative effect of such additive in the
2 diet of man or animals, taking into account any chemi-
3 cally or pharmacologically related substance or sub-
4 stances in such diet; and

5 “(C) appropriate safety factors for the use of
6 animal experimentation data.

7 “Regulation Issued on Secretary's Initiative

8 “(d) The Secretary may at any time, upon his own
9 initiative, propose the issuance of a regulation prescribing;
10 with respect to any particular use of a food additive, the
11 conditions under which such additive may be safely used.
12 After the thirtieth day following publication of such a pro-
13 posal, the Secretary may by order establish a regulation
14 based upon the proposal, unless within such thirty-day period
15 a person files a petition under subsection (b) with respect
16 to such additive and requests that the proposal, or any
17 question of fact raised thereby, be referred to an advisory
18 committee appointed pursuant to subsection (e) of this
19 section.

20 “Reference to Advisory Committee

21 “(e) (1) At any time before, or within thirty days
22 after, publication of an order issued under subsection (c)
23 or (d) of this section, the petitioner may request that the
24 petition or order thereon, or the Secretary's proposal, or

1 any question raised by such petition, order, or proposal, be
2 referred to an advisory committee. Upon such request, or
3 if the Secretary within such time deems such a referral
4 necessary, the Secretary shall forthwith appoint an advisory
5 committee of competent experts to review the petition,
6 order, or proposal, or question, as the case may be, and to
7 make a report and recommendation thereon. Each such
8 advisory committee shall be composed of experts, qualified
9 in the subject matter of the petition, order, proposal, or
10 question, as the case may be, and of adequately diversified
11 professional background selected by the National Academy
12 of Sciences, except that in the event of the inability or
13 refusal of the National Academy of Sciences to act, the
14 Secretary shall select the members of the committee. The
15 size of the committee shall be determined by the Secretary.
16 Members of an advisory committee shall receive as com-
17 pensation for their services a reasonable per diem, which
18 the Secretary shall by rules and regulations prescribe, for
19 time actually spent in the work of the committee, and shall
20 in addition be reimbursed for their necessary traveling and
21 subsistence expenses while so serving away from their places
22 of residence. The members shall not be subject to any other
23 provisions of law regarding the appointment and compen-
24 sation of employees of the United States. The Secretary
25 shall furnish the committee with adequate clerical and other

1 assistance, and shall by rules and regulations prescribe the
2 procedure to be followed by the committee. The Secretary
3 shall refer the petition, order, or proposal, or question, as
4 the case may be, to the advisory committee so appointed,
5 and furnish such committee all the data before him. A
6 person who has filed a petition or who has requested the
7 referral of an order, proposal, or question, to an advisory
8 committee, as well as representatives to the Department of
9 Health, Education, and Welfare, shall have the right to
10 consult with such advisory committee in connection with the
11 matter referred to it."

12 “(2) Within sixty days after the date of such referral,
13 or within an additional thirty days if the committee deems
14 such additional time necessary, the committee shall, after
15 independent study of the data furnished to it by the Sec-
16 retary and other data before it, certify to the Secretary a
17 report and recommendations, together with all underlying
18 data and a statement of the reasons or basis for the recom-
19 mendations. With thirty days after such certification,
20 and after giving due consideration to all data then before
21 him, including such report, recommendations, underlying
22 data, and statement, and to any prior order issued by him
23 in connection with such matter, the Secretary shall confirm
24 or modify any order theretofore issued or, if no such order
25 has been issued, shall by order establish a regulation pre-

1 scribing, with respect to any particular use of the food
2 additive involved, the conditions under which such additive
3 may be safely used or shall, by order, deny the petition.

4 ~~“(3)~~ The Secretary may by regulation condition re-
5 ferrals to advisory committees pursuant to this subsection
6 upon the payment, by the person requesting the referral, of
7 fees to defray the costs arising by reason of such referrals;
8 Such fees, including advance deposits to cover such fees, shall
9 be available, until expended, for paying ~~(directly or by way~~
10 ~~of reimbursement of the applicable appropriation)~~ the ex-
11 penses of advisory committees under this subsection and other
12 expenses arising by reason of referrals to such committees,
13 and for refunds of excess payments.

14 “Publication and Effective Date of Orders

15 ~~“(f)~~ Any order, including any regulation established
16 by such order, issued under subsection ~~(c)~~, ~~(d)~~, or ~~(e)~~ of
17 this section, shall be published and shall be effective upon
18 publication, but the Secretary may stay such effectiveness
19 if, after issuance of such order, the order or any question
20 related thereto is referred to an advisory committee pursu-
21 ant to subsection ~~(c)~~ or if a hearing is sought with respect
22 to such order pursuant to subsection ~~(g)~~.

23 “Objections and Public Hearing

24 ~~“(g)~~ (1) Within thirty days after publication of an
25 order made pursuant to subsection ~~(c)~~, ~~(d)~~, or ~~(e)~~ of this

1 section, any person adversely affected by such an order may
2 file objections thereto with the Secretary, specifying with
3 particularity the provisions of the order deemed objection-
4 able, stating reasonable grounds therefor, and requesting a
5 public hearing upon such objections. —The Secretary shall
6 thereupon, after due notice, hold such public hearing for the
7 purpose of receiving evidence relevant and material to the
8 issues raised by such objections. Any report, recommenda-
9 tions, underlying data, and reasons certified to the Secretary
10 by an advisory committee shall be made a part of the record
11 of the hearing if relevant and material, subject to the provi-
12 sions of section 7 (c) of the Administrative Procedure Act
13 (5 U. S. C., sec. 1006 (c)). The advisory committee shall
14 designate a member to appear and testify at any such hear-
15 ing with respect to the report and recommendations of such
16 committee upon request of the Secretary, the petitioner, or
17 the officer conducting the hearing, but this shall not preclude
18 any other member of the advisory committee from appearing
19 and testifying at such hearing. As soon as practicable after
20 completion of the hearing, the Secretary shall by order act
21 upon such objections and make such order public.

22 “(2) Such order shall be based upon a fair evaluation
23 of the entire record at such hearing, including any report,
24 recommendations, underlying data, and reasons certified to
25 the Secretary by an advisory committee, and shall include a

1 statement setting forth in detail the findings and conclusions
2 upon which the order is based.

3 ~~“(3)~~ The Secretary shall specify in the order the date
4 on which it shall take effect, except that it shall not be
5 made to take effect prior to the ninetieth day after its
6 publication, unless the Secretary finds that emergency con-
7 ditions exist necessitating an earlier effective date, in which
8 event the Secretary shall specify in the order his findings as
9 to such conditions.

10 “Judicial Review

11 ~~“(h) (1)~~ In a case of actual controversy as to the
12 validity of any order issued under subsection ~~(g)~~, including
13 any order thereunder with respect to amendment or repeal of
14 a regulation issued under this section, any person who will
15 be adversely affected by such order may obtain judicial
16 review by filing in the United States Court of Appeals for
17 the circuit wherein such person resides or has his principal
18 place of business, or in the United States Court of Appeals
19 for the District of Columbia Circuit, within sixty days after
20 the entry of such order, a petition praying that the order
21 be set aside in whole or in part.

22 ~~“(2)~~ A copy of such petition shall be forthwith served
23 upon the Secretary, or upon any officer designated by him
24 for that purpose, and thereupon the Secretary shall certify
25 and file in the court a transcript of the proceedings and the

1 record on which he based his order. Upon such filing, the
2 court shall have exclusive jurisdiction to affirm or set aside
3 the order complained of in whole or in part. The findings
4 of the Secretary with respect to questions of fact shall be
5 sustained if based upon a fair evaluation of the entire record
6 at such hearing, including any report, recommendation,
7 underlying data, and reasons certified to the Secretary by an
8 advisory committee.

9 “(3) If application is made to the court for leave to
10 adduce additional evidence, the court may order such addi-
11 tional evidence to be taken before the Secretary and to be
12 adduced upon the hearing in such manner and upon such
13 terms and conditions as to the court may seem proper, if
14 such evidence is material and there were reasonable grounds
15 for failure to adduce such evidence in the proceedings below.
16 The Secretary may modify his findings as to the facts and
17 order by reason of the additional evidence so taken, and
18 shall file with the court such modified findings and order.

19 “(4) The judgment of the court affirming or setting
20 aside, in whole or in part, any order under this section shall
21 be final, subject to review by the Supreme Court of the
22 United States upon certiorari or certification as provided
23 in section 1254 of title 28 of the United States Code. The
24 commencement of proceedings under this section shall not,
25 unless specifically ordered by the court to the contrary,

1 operate as a stay of an order. The court shall advance on
2 the docket and expedite the disposition of all causes filed
3 therein pursuant to this section.

4 “~~(5)~~ The court, on such judicial review, shall not sustain
5 the order of the Secretary if he failed to comply with any
6 requirement imposed on him by subsection ~~(g)~~ ~~(2)~~ of this
7 section.

8 “Amendment or Repeal of Regulations

9 “~~(i)~~ The Secretary shall by regulation prescribe the
10 procedure by which regulations under the foregoing pro-
11 visions of this section may be amended or repealed, and
12 such procedure shall conform to the procedure provided
13 in this section for the promulgation of such regulations, in-
14 cluding the appointment of advisory committees and the
15 procedure for referring matters to such committees.

16 “Exemptions for Investigational Use

17 “~~(j)~~ Without regard to subsections ~~(b)~~ to ~~(i)~~, inclu-
18 sive, of this section, the Secretary shall by regulation provide
19 for exempting from the requirements of this section any
20 food additive, and any food bearing or containing such addi-
21 tive, intended solely for investigational use by qualified ex-
22 perts when in his opinion such exemption is consistent with
23 the public health.”

24 SEC. 5. Section 301 ~~(j)~~ of such Act is amended by in-
25 serting “409” after “404.”

1 SEC. 6. ~~(a)~~ Except as provided in subsections ~~(b)~~ and
2 ~~(c)~~ of this section, this Act shall take effect on the date of
3 its enactment.

4 ~~(b)~~ Except as provided in subsection ~~(c)~~ of this section,
5 section 3 of this Act shall take effect on the one hundred and
6 eightieth day after the date of enactment of this Act.

7 ~~(c)~~ With respect to any particular commercial use of a
8 food additive, if such use was made of such additive before
9 January 1, 1958, section 3 of this Act shall take effect—

10 ~~(1)~~ either ~~(A)~~ one year after the effective date
11 established in subsection ~~(b)~~ of this section, or ~~(B)~~ at
12 the end of such additional period ~~(but not later than~~
13 ~~two years from such effective date established in sub-~~
14 ~~section (b))~~ as the Secretary of Health, Education, and
15 Welfare may prescribe on the basis of a finding that
16 such extension involves no undue risk to the public
17 health and that conditions exist which necessitate the
18 prescribing of such an additional period, or

19 ~~(2)~~ on the date on which an order with respect to
20 such use under section 409 of the Federal Food, Drug,
21 and Cosmetic Act becomes effective,
22 whichever date first occurs.

23 SEC. 7. Nothing in this Act shall be construed to ex-
24 empt any meat or meat food product or any person from

1 any requirement imposed by or pursuant to the Meat Inspe-
2 tion Act of March 4, 1907, 34 Stat. 1260, as amended and
3 extended (~~21 U. S. C. 71 and the following~~).

4 *That this Act may be cited as the "Food Additives Amend-*
5 *ment of 1958".*

6 *SEC. 2. Section 201, as amended, of the Federal Food,*
7 *Drug, and Cosmetic Act is further amended by adding at*
8 *the end of such section the following new paragraphs:*

9 *"(s) The term 'food additive' means any substance the*
10 *intended use of which results or may reasonably be expected*
11 *to result, directly or indirectly, in its becoming a component*
12 *or otherwise affecting the characteristics of any food (includ-*
13 *ing any substance intended for use in producing, manufac-*
14 *turing, packing, processing, preparing, treating, packaging,*
15 *transporting, or holding food; and including any source of*
16 *radiation intended for any such use), if such substance is not*
17 *generally recognized, among experts qualified by scientific*
18 *training and experience to evaluate its safety, as having been*
19 *adequately shown through scientific procedures (or, in the*
20 *case of a substance used in food prior to January 1, 1958,*
21 *through either scientific procedures or experience based on*
22 *common use in food) to be safe under the conditions of its*
23 *intended use; except that such term does not include—*

24 *"(1) a pesticide chemical in or on a raw agricultural*
25 *commodity; or*

1 “(2) a pesticide chemical to the extent that it is
2 intended for use or is used in the production, storage, or
3 transportation of any raw agricultural commodity; or

4 “(3) any substance used in accordance with a sanc-
5 tion or approval granted prior to the enactment of this
6 paragraph pursuant to this Act or the Meat Inspection
7 Act of March 4, 1907 (34 Stat. 1260), as amended and
8 extended (21 U. S. C. 71 and the following).

9 “(t) The term ‘safe’, as used in paragraph (s) of this
10 section and in section 409, has reference to the health of man
11 or animal.”

12 SEC. 3. (a) Clause (2) of section 402 (a), as amended,
13 of such Act is amended to read as follows: “(2) (A) if it
14 bears or contains any added poisonous or added deleterious
15 substance (except a pesticide chemical in or on a raw agri-
16 cultural commodity and except a food additive) which is un-
17 safe within the meaning of section 406, or (B) if it is a
18 raw agricultural commodity and it bears or contains a pesti-
19 cide chemical which is unsafe within the meaning of section
20 408 (a), or (C) if it is, or it bears or contains, any food
21 additive which is unsafe within the meaning of section 409:
22 Provided, That where a pesticide chemical has been used in
23 or on a raw agricultural commodity in conformity with an
24 exemption granted or a tolerance prescribed under section
25 408 and such raw agricultural commodity has been subjected

1 to processing such as canning, cooking, freezing, dehydrat-
 2 ing, or milling, the residue of such pesticide chemical remain-
 3 ing in or on such processed food shall, notwithstanding the
 4 provisions of sections 406 and 409, not be deemed unsafe if
 5 such residue in or on the raw agricultural commodity has been
 6 removed to the extent possible in good manufacturing prac-
 7 tice and the concentration of such residue in the processed
 8 food when ready to eat is not greater than the tolerance
 9 prescribed for the raw agricultural commodity;”.

10 (b) Section 402 (a), as amended, of such Act is further
 11 amended by striking out the period at the end thereof and
 12 inserting in lieu thereof a semicolon and the following: “or
 13 (7) if it has been intentionally subjected to radiation, unless
 14 the use of the radiation was in conformity with a regulation
 15 or exemption in effect pursuant to section 409.”

16 (c) The first sentence of section 406 (a) of such
 17 Act is amended by striking out “clause (2)” wherever it
 18 appears in such sentence and inserting in lieu thereof “clause
 19 (2) (A)”.

20 SEC. 4. Chapter IV of such Act is amended by adding
 21 at the end thereof the following new section:

22 “FOOD ADDITIVES

23 “Unsafe Food Additives

24 “SEC. 409. (a) A food additive shall, with respect to
 25 any particular use or intended use of such additives, be

1 *deemed to be unsafe for the purposes of the application*
2 *of clause (2) (C) of section 402 (a), unless—*

3 *“(1) it and its use or intended use conform to the*
4 *terms of an exemption which is in effect pursuant to sub-*
5 *section (i) of this section; or*

6 *“(2) there is in effect, and it and its use or*
7 *intended use are in conformity with, a regulation issued*
8 *under this section prescribing the conditions under*
9 *which such additive may be safely used.*

10 *While such a regulation relating to a food additive is in*
11 *effect, a food shall not, by reason of bearing or containing*
12 *such an additive in accordance with the regulation, be con-*
13 *sidered adulterated within the meaning of clause (1) of*
14 *section 402 (a).*

15 *“Petition To Establish Safety*

16 *“(b) (1) Any person may, with respect to any intended*
17 *use of a food additive, file with the Secretary a petition pro-*
18 *posing the issuance of a regulation prescribing the conditions*
19 *under which such additive may be safely used.*

20 *“(2) Such petition shall, in addition to any explanatory*
21 *or supporting data, contain—*

22 *“(A) the name and all pertinent information con-*
23 *cerning such food additive, including, where available,*
24 *its chemical identity and composition;*

25 *“(B) a statement of the conditions of the proposed*

1 *use of such additive, including all directions, recommen-*
2 *dations, and suggestions proposed for the use of such*
3 *additive, and including specimens of its proposed label-*
4 *ing;*

5 *“(C) all relevant data bearing on the physical or*
6 *other technical effect such additive is intended to pro-*
7 *duce, and the quantity of such additive required to*
8 *produce such effect;*

9 *“(D) a description of practicable methods for deter-*
10 *mining the quantity of such additive in or on food, and*
11 *any substance formed in or on food, because of its use;*
12 *and*

13 *“(E) full reports of investigations made with respect*
14 *to the safety for use of such additive, including full*
15 *information as to the methods and controls used in con-*
16 *ducting such investigations.*

17 *“(3) Upon request of the Secretary, the petitioner shall*
18 *furnish (or, if the petitioner is not the manufacturer of such*
19 *additive, the petitioner shall have the manufacturer of such*
20 *additive furnish, without disclosure to the petitioner) a full*
21 *description of the methods used in, and the facilities and*
22 *controls used for, the production of such additive.*

23 *“(4) Upon request of the Secretary, the petitioner shall*

1 furnish samples of the food additive involved, or articles
2 used as components thereof, and of the food in or on which
3 the additive is proposed to be used.

4 “(5) Notice of the regulation proposed by the petitioner
5 shall be published in general terms by the Secretary within
6 thirty days after filing.

7 “Action on the Petition

8 “(c) (1) The Secretary shall—

9 “(A) by order establish a regulation (whether or
10 not in accord with that proposed by the petitioner)
11 prescribing, with respect to one or more proposed uses
12 of the food additive involved, the conditions under
13 which such additive may be safely used (including, but
14 not limited to, specifications as to the particular food or
15 classes of food in or in which such additive may be
16 used, the maximum quantity which may be used or per-
17 mitted to remain in or on such food, the manner in
18 which such additive may be added to or used in or on
19 such food, and any directions or other labeling or
20 packaging requirements for such additive deemed
21 necessary by him to assure the safety of such use),
22 and shall notify the petitioner of such order and the
23 reasons for such action; or

1 “(B) by order deny the petition, and shall notify
2 the petitioner of such order and of the reasons for such
3 action.

4 “(2) The order required by paragraph (1) (A) or
5 (B) of this subsection shall be issued within ninety days
6 after the date of filing of the petition, except that the Secre-
7 tary may (prior to such ninetieth day), by written notice
8 to the petitioner, extend such ninety-day period to such
9 time (not more than one hundred and eighty days after the
10 date of filing of the petition) as the Secretary deems neces-
11 sary to enable him to study and investigate the petition.

12 “(3) No such regulation shall issue if a fair evaluation
13 of the data before the Secretary—

14 “(A) fails to establish that the proposed use of the
15 food additive, under the conditions of use to be speci-
16 fied in the regulation, will be safe; or

17 “(B) shows that the proposed use of the additive
18 would promote deception of the consumer in violation
19 of this Act or would otherwise result in adulteration
20 or in misbranding of food within the meaning of this Act.

21 “(4) If, in the judgment of the Secretary, based upon
22 a fair evaluation of the data before him, a tolerance limita-
23 tions is required in order to assure that the proposed use
24 of an additive will be safe, the Secretary—

1 “(A) shall not fix such tolerance limitation at a
2 level higher than he finds to be reasonably required to
3 accomplish the physical or other technical effect for
4 which such additive is intended; and

5 “(B) shall not establish a regulation for such pro-
6 posed use if he finds upon a fair evaluation of the data
7 before him that such data do not establish that such use
8 would accomplish the intended physical or other techni-
9 cal effect.

10 “(5) In determining, for the purposes of this section,
11 whether a proposed use of a food additive is safe, the Sec-
12 retary shall consider among other relevant factors—

13 “(A) the probable consumption of the additive
14 and of any substance formed in or on food because of
15 the use of the additive;

16 “(B) the cumulative effect of such additive in the
17 diet of man or animals, taking into account any chemi-
18 cally or pharmacologically related substance or sub-
19 stances in such diet; and

20 “(C) safety factors which in the opinion of experts
21 qualified by scientific training and experience to evaluate
22 the safety of food additives are generally recognized as
23 appropriate for the use of animal experimentation data.

1 *“Regulation Issued on Secretary’s Initiative*

2 *“(d) The Secretary may at any time, upon his own*
3 *initiative, propose the issuance of a regulation prescribing,*
4 *with respect to any particular use of a food additive, the*
5 *conditions under which such additive may be safely used,*
6 *and the reasons therefor. After the thirtieth day following*
7 *publication of such a proposal, the Secretary may by order*
8 *establish a regulation based upon the proposal.*

9 *“Publication and Effective Date of Orders*

10 *“(e) Any order, including any regulation established*
11 *by such order, issued under subsection (c) or (d) of this*
12 *section, shall be published and shall be effective upon publi-*
13 *cation, but the Secretary may stay such effectiveness if, after*
14 *issuance of such order, a hearing is sought with respect to*
15 *such order pursuant to subsection (f).*

16 *“Objections and Public Hearing*

17 *“(f) (1) Within thirty days after publication of an*
18 *order made pursuant to subsection (c) or (d) of this*
19 *section, any person adversely affected by such an order may*
20 *file objections thereto with the Secretary, specifying with*
21 *particularity the provisions of the order deemed objection-*
22 *able, stating reasonable grounds therefor, and requesting a*
23 *public hearing upon such objections. The Secretary shall,*
24 *after due notice, as promptly as possible hold such public*
25 *hearing for the purpose of receiving evidence relevant and*

1 material to the issues raised by such objections. As soon as
2 practicable after completion of the hearing, the Secretary
3 shall by order act upon such objections and make such order
4 public.

5 “(2) Such order shall be based upon a fair evaluation
6 of the entire record at such hearing, and shall include a
7 statement setting forth in detail the findings and conclusions
8 upon which the order is based.

9 “(3) The Secretary shall specify in the order the date
10 on which it shall take effect, except that it shall not be
11 made to take effect prior to the ninetieth day after its
12 publication, unless the Secretary finds that emergency con-
13 ditions exist necessitating an earlier effective date, in which
14 event the Secretary shall specify in the order his findings as
15 to such conditions.

16 “Judicial Review

17 “(g) (1) In a case of actual controversy as to the
18 validity of any order issued under subsection (f), including
19 any order thereunder with respect to amendment or repeal of
20 a regulation issued under this section, any person who will
21 be adversely affected by such order may obtain judicial
22 review by filing in the United States Court of Appeals for
23 the circuit wherein such person resides or has his principal
24 place of business, or in the United States Court of Appeals
25 for the District of Columbia Circuit, within sixty days after

1 the entry of such order, a petition praying that the order
2 be set aside in whole or in part.

3 “(2) A copy of such petition shall be forthwith served
4 upon the Secretary, or upon any officer designated by him
5 for that purpose, and thereupon the Secretary shall certify
6 and file in the court a transcript of the proceedings and the
7 record on which he based his order. Upon such filing, the
8 court shall have exclusive jurisdiction to affirm or set aside
9 the order complained of in whole or in part. The findings
10 of the Secretary with respect to questions of fact shall be
11 sustained if based upon a fair evaluation of the entire record
12 at such hearing. The court shall advance on the docket and
13 expedite the disposition of all causes filed therein pursuant
14 to this section.

15 “(3) The court, on such judicial review, shall not sustain
16 the order of the Secretary if he failed to comply with any
17 requirement imposed on him by subsection (f) (2) of this
18 section.

19 “(4) If application is made to the court for leave to
20 adduce additional evidence, the court may order such addi-
21 tional evidence to be taken before the Secretary and to be
22 adduced upon the hearing in such manner and upon such
23 terms and conditions as to the court may seem proper, if
24 such evidence is material and there were reasonable grounds
25 for failure to adduce such evidence in the proceedings below.

1 *The Secretary may modify his findings as to the facts and*
2 *order by reason of the additional evidence so taken, and*
3 *shall file with the court such modified findings and order.*

4 “(5) *The judgment of the court affirming or setting*
5 *aside, in whole or in part, any order under this section shall*
6 *be final, subject to review by the Supreme Court of the*
7 *United States upon certiorari or certification as provided*
8 *in section 1254 of title 28 of the United States Code. The*
9 *commencement of proceedings under this section shall not,*
10 *unless specifically ordered by the court to the contrary,*
11 *operate as a stay of an order.*

12 *“Amendment or Repeal of Regulations*

13 “(h) *The Secretary shall by regulation prescribe the*
14 *procedure by which regulations under the foregoing pro-*
15 *visions of this section may be amended or repealed, and*
16 *such procedure shall conform to the procedure provided*
17 *in this section for the promulgation of such regulations.*

18 *“Exemptions for Investigational Use*

19 “(i) *Without regard to subsections (b) to (h), inclu-*
20 *sive, of this section, the Secretary shall by regulation provide*
21 *for exempting from the requirements of this section any*
22 *food additive, and any food bearing or containing such addi-*
23 *tive, intended solely for investigational use by qualified ex-*
24 *perts when in his opinion such exemption is consistent with*
25 *the public health.”*

1 *SEC. 5. Section 301 (j) of such Act is amended by*
2 *inserting "409," after "404,".*

3 *SEC. 6. (a) Except as provided in subsections (b) and*
4 *(c) of this section, this Act shall take effect on the date of*
5 *its enactment.*

6 *(b) Except as provided in subsection (c) of this section,*
7 *section 3 of this Act shall take effect on the one hundred and*
8 *eightieth day after the date of enactment of this Act.*

9 *(c) With respect to any particular commercial use of a*
10 *food additive, if such use was made of such additive before*
11 *January 1, 1958, section 3 of this Act shall take effect—*

12 *(1) either (A) one year after the effective date*
13 *established in subsection (b) of this section, or (B) at*
14 *the end of such additional period (but not later than*
15 *two years from such effective date established in sub-*
16 *section (b)) as the Secretary of Health, Education, and*
17 *Welfare may prescribe on the basis of a finding that*
18 *such extension involves no undue risk to the public*
19 *health and that conditions exist which necessitate the*
20 *prescribing of such an additional period, or*

21 *(2) on the date on which an order with respect to*
22 *such use under section 409 of the Federal Food, Drug,*
23 *and Cosmetic Act becomes effective,*
24 *whichever date first occurs.*

25 *SEC. 7. Nothing in this Act shall be construed to exempt*

1 *any meat or meat food product or any person from any*
2 *requirement imposed by or pursuant to the Meat Inspection*
3 *Act of March 4, 1907, 34 Stat. 1260, as amended and*
4 *extended (21 U. S. C. 71 and the following).*

85TH CONGRESS
2D SESSION

H. R. 13254

[Report No. 2284]

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Mr. WILLIAMS of Mississippi

JULY 1, 1958

Referred to the Committee on Interstate and Foreign
Commerce

JULY 28, 1958

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

H. R. 13254

(Type in full)

A BILL

For the relief of the people of the State of New York, and for other purposes.

Enacted by the Senate and Assembly of the State of New York, January 1, 1911.

Chapter 100

Section 1

Section 2

Section 3

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF BUDGET AND FINANCE
(For Department Staff Only)

Issued August 14, 1958
For actions of August 13, 1958
85th-2d, No. 139

CONTENTS

Acreage allotments.....	32		
Appropriations.....	19,22		
Area development.....	25		
Cotton.....	15,32		
Country life.....	29		
Education.....	16,23		
Ethics.....	35		
Farm loans.....	2		
Farm program.....	1,15	Investigations.....	24
Food additives.....	6	Lands.....	7
Forestry.....	18	Legislative program.....	22
Fruits.....	30	Marketing.....	30
Health.....	31	Minerals.....	11
Housing.....	3	Public Law 480.....	27
Humane slaughter.....	3	Reclamation.....	14,34
Industrial research.....	26	Research.....	11,12,31,33
Information.....	13,36	Rice.....	15,32
		Roads.....	5
		Saline water.....	17
		School lunches.....	10
		Small business.....	20
		Taxation.....	4
		Transportation.....	9
		Vegetables.....	30
		Water.....	11,21,23
		Wool.....	15

HIGHLIGHTS: House cleared for President: Humane slaughter bill; USDA insured loans bill. Rep. McCormack announced farm bill to be considered today (Aug. 14). Senate committee reported supplemental appropriation bill (to be considered today, Aug. 14). Several Senators urged passage of cotton, rice, and wool legislation. Senate passed education bill. Sen. Proxmire introduced and discussed bill to extend marketing orders to producers of fresh fruits and vegetables. Sen. Symington submitted and discussed measure to freeze cotton and rice acreage allotments.

HOUSE

- FARM PROGRAM.** Rep. McCormack announced that S. 4071, the farm bill, would be considered today, Aug. 14, under suspension of the rules. (p. 16013) Rep. Cooley inserted a copy of the bill to be considered, which he stated would be an amendment to the bill as passed by the Senate. (pp. 16026-29)
- FARM LOANS.** Passed under suspension of the rules S. 3333, to facilitate the insurance of farm ownership and soil and water conservation loans. This bill will now be sent to the President. (pp. 16029-30) See Digest 137 for provisions of the bill.
- HUMANE SLAUGHTER.** Concurred in the Senate amendments to H. R. 8308, to provide for the humane slaughter of livestock. This bill will now be sent to the President. (p. 16029) See Digest 128 for a summary of the Senate amendments.
- EXCISE TAXES.** Received the conference report on H. R. 7125, to make technical changes in the Federal excise tax laws (H. Rept. 2596). House conferees were appointed earlier in the day. Senate conferees have been appointed. pp. 15956, 16053-56

5. ROADS. Concurred in the Senate amendment to H. R. 12776, to revise, codify, and enact into law, title 23 of the U. S. Code entitled "Highways." This bill will now be sent to the President. pp. 15998-99
6. FOOD ADDITIVES. Passed under suspension of the rules H. R. 13254, to amend the Federal Food, Drug, and Cosmetic Act so as to prohibit the use in food of additives which have not been adequately tested to establish their safety. pp. 16013-26
7. LANDS. Concurred in the Senate amendment to H. R. 4635, to provide for the settlement and entry of public lands in Alaska containing coal, oil, or gas under Sec. 10 of the act of May 14, 1898. This bill will now be sent to the President. p. 16034
8. HOUSING. Rep. Mack urged passage of S. 4035, the omnibus housing bill, before Congress adjourns. p. 16036
9. TRANSPORTATION. Rep. Tollefson referred to certain foreign criticism of the cargo preference legislation, which requires that at least 50 percent of U. S. shipments under the foreign aid program be shipped in American vessels, and stated that "I am convinced that Congress will not relax its views with respect to" this shipping requirement. p. 16036
10. SCHOOL LUNCHES. The District of Columbia Committee reported with amendment S. 1764, to authorize payment of the cost of free lunches for needy children in the D. C. public schools (H. Rept. 2588). p. 16056
11. MINERALS; WATER RESOURCES. Agreed to the Senate amendment to H. R. 11123, to authorize Interior to perform surveys, investigations, and research in geology, biology, minerals and water resources. This bill will now be sent to the President. p. 16034
12. RESEARCH. The Interstate and Foreign Commerce Committee ordered reported S. 4039, to authorize the head of any Government agency now making contracts for research to grant funds for the support of such research. p. D844
13. INFORMATION. Received a report from the Government Operations Committee "pertaining to information from Federal departments and agencies" (H. Rept. 2578). p. 16056
14. RECLAMATION. Received from Interior a report on Red Willow Dam and Reservoir and associated works, and Frenchman-Cambridge division, Missouri River Basin project, Nebr. p. 16056

SENATE

15. FARM PROGRAM. Sen. McClellan urged the passage of legislation this session to prevent reductions in cotton and rice acreage. Sen. Stennis concurred in his opposition to adjourning until the farm legislation is passed. Sen. Johnson stated: "Too many people in this field have been too adamant," and urged that a compromise farm bill be worked out. Sens. Johnston, Jordan, and Hill agreed that farm legislation is necessary. pp. 15844-5
Sens. Mansfield, Barrett, Allott, and Thye urged the passage of the Wool Act extension bill, and stated that the woolgrowers would be endangered if the law were not extended this session. pp. 15856-8

The SPEAKER. Is there objection to the request of the gentleman from Pennsylvania?

Mr. KEATING. Mr. Speaker, reserving the right to object; does this amendment provide the same relief in different language?

Mr. WALTER. That is right. The bill changes the status of a widow of a United States citizen.

Mr. KEATING. That is not a change in her actual status but rather her legal status.

Mr. WALTER. Yes; it changes her legal status under the immigration laws by preserving her nonquota classification.

Mr. KEATING. Mr. Speaker, I withdraw my reservation of objection.

The SPEAKER. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

The Senate amendment was concurred in.

A motion to reconsider was laid on the table.

GRANTING OF PERMANENT RESIDENCE TO CERTAIN ALIENS

Mr. WALTER. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the concurrent resolution (H. Con. Res. 321) approving the granting of the status of permanent resident to certain aliens, with amendments of the Senate thereto, and concur in the Senate amendments.

The Clerk read the title of the concurrent resolution.

The Clerk read the Senate amendments, as follows:

Page 3, strike out lines 6 and 7.

Page 4, strike out line 7.

Page 6, strike out line 23.

Page 8, after line 17, insert:

"A-10256998, Leung, Chun.

"A-9764946, On, Lo.

"A-8248567, Blaszkowski, Henryk.

"A-9777521, Kuan, Ho."

The SPEAKER. Is there objection to the request of the gentleman from Pennsylvania?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

DWIGHT S. SHARER

Mr. LANE. Mr. Speaker, I ask unanimous consent for the present consideration of the bill (S. 784) for the relief of Dwight S. Sharer.

The Clerk read the title of the bill.

The SPEAKER. Is there objection to the request of the gentleman from Massachusetts?

There was no objection.

The Clerk read the bill, as follows:

Be it enacted, etc., That Dwight S. Sharer, postmaster at Mount Morris, Ill., is relieved from liability for repayment to the United States of the amount of \$6,400, representing the amount due the United States on account of the embezzlement of post office funds by Dale M. Elzer, a former clerk in the post office at Mount Morris, Ill., during the period from July 1951, through June 1954, inclusive.

The bill was ordered to be read a third time, was read the third time, and passed, and a motion to reconsider was laid on the table.

COMMITTEE ON WAYS AND MEANS

Mr. McCORMACK. Mr. Speaker, I ask unanimous consent that the Committee on Ways and Means may have until midnight tonight to file conference reports on the bill, H. R. 7125, the Excise Technical Changes Act of 1958 and H. R. 8381, the Technical Amendments Act of 1958.

The SPEAKER. Is there objection to the request of the gentleman from Massachusetts?

There was no objection.

LEGISLATIVE PROGRAM

Mr. McCORMACK. Mr. Speaker, I desire to make a brief announcement. In connection with the bill that will come up under suspension tomorrow, I wish to announce that the bill is a farm bill.

AMENDING FEDERAL FOOD, DRUG AND COSMETIC ACT—USE OF ADDITIVES IN FOOD

Mr. HARRIS. Mr. Speaker, I move to suspend the rules and pass the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, as amended.

The Clerk read as follows:

Be it enacted, etc., That this act may be cited as the "Food Additives Amendment of 1958."

SEC. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

"(s) The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

"(t) The term 'safe', as used in paragraph (s) of this section and in section 409,

has reference to the health of man or animal."

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity, in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;"

(b) Section 402 (a), as amended, of such act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

(c) The first sentence of section 406 (a) of such act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)."

SEC. 4. Chapter IV of such act is amended by adding at the end thereof the following new section:

"FOOD ADDITIVES

"Unsafe food additives

"SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

"Petition to establish safety

"(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to any explanatory or supporting data, contain—

"(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

"(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and

including specimens of its proposed labeling;

"(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

"(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

"(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

"(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

"(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within 30 days after filing.

"Action on the petition"

"(c) (1) The Secretary shall—

"(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

"(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

"(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within 90 days after the date of filing of the petition, except that the Secretary may (prior to such 19th day), by written notice to the petitioner, extend such 90-day period to such time (not more than 180 days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

"(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

"(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

"(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this act or would, otherwise result in adulteration or in misbranding of food within the meaning of this act.

"(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

"(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

"(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

"(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

"(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

"(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

"(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

"Regulation issued on Secretary's initiative"

"(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

"Publication and effective date of orders"

"(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

"Objections and public hearing"

"(f) (1) Within 30 days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

"(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

"(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the 90th day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"Judicial review"

"(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such

order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part.

"(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

"(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

"(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

"(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

"Amendment or repeal of regulations"

"(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

"Exemptions for investigational use"

"(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

SEC. 5. Section 301 (j) of such act is amended by inserting "409," after "404."

SEC. 6. (a) Except as provided in subsections (b) and (c) of this section, this act shall take effect on the date of its enactment.

(b) Except as provided in subsection (c) of this section, section 3 of this act shall take effect on the 180th day after the date of enactment of this act.

(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this act shall take effect—

(1) either (A) 1 year after the effective date established in subsection (b) of this section, or (B) at the end of such additional period

(but not later than 2 years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective,

whichever date first occurs.

SEC. 7. Nothing in this act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

The SPEAKER. Is a second demanded?

Mr. O'HARA of Illinois. Mr. Speaker, I demand a second.

The SPEAKER. Without objection a second will be considered as ordered.

There was no objection.

Mr. HARRIS. Mr. Speaker, I yield myself such time as I may require.

Mr. Speaker, the food additive legislation which the Committee on Interstate and Foreign Commerce has reported unanimously bears the imprint of JAMES J. DELANEY, our esteemed colleague from New York. Without JIM DELANEY's efforts on behalf of this legislation there might well not be any food additive legislation and it is therefore fitting for the Committee on Interstate and Foreign Commerce to pay tribute to our colleague today.

During the 81st Congress JIM DELANEY was the chairman of the Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics. This committee became known as the Delaney Committee and after extended hearings, the select committee filed a report in 1952 urging an amendment to the present Food and Drug Act covering chemicals in food and cosmetics.

Mr. DELANEY testified before our committee during the 83d Congress, the 84th Congress, and again during the 85th Congress, and his continuing efforts on behalf of this legislation have finally resulted in the reporting of H. R. 13254.

The purpose of the legislation is twofold:

First, to protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and second, to advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production of cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot

prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofore voluntarily assumed.

Although there has been complete agreement as to the need for this legislation, there have been differences between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

During the 81st Congress, a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics—better known as the Delaney committee, named after its chairman, Congressman JAMES J. DELANEY—was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in this respect. After extended hearings, the committee on June 30, 1952, filed a report—House Report No. 2356, 82d Congress, 2d session—urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of the report were introduced by Congressman DELANEY and referred to this committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, the committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy

Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

During the 85th Congress, the Subcommittee on Health and Science held 11 days of hearings on 9 bills. The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee the scientific background with regard to the testing and evaluating of the safety of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of the hearings and after consideration of the various bills, the chairman of the subcommittee, Congressman JOHN BELL WILLIAMS, of Mississippi, introduced a clean bill—H. R. 13254—which was reported unanimously by the subcommittee to the full committee.

The full committee unanimously reported the bill with one amendment which strikes out all after the enacting clause and inserts in place of the introduced bill a substitute. The principal difference between the proposed committee amendment and the introduced bill is the elimination of the provisions in the introduced bill relating to scientific advisory committees. The remaining differences are the result of clerical, technical, and clarifying changes.

Subsequently to the reporting of the bill, as amended in the full committee, the committee adopted unanimously a further amendment to the amendment. This amendment was suggested by Mr. DELANEY who over the years since he was the chairman of a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, has expressed his deep and abiding interest in this subject. While the committee felt that the bill as reported by the committee includes the matter covered by the Delaney amendment in the general language contained in the bill, there was no objection to the addition of the amendment suggested by Mr. DELANEY. This amendment would be inserted on page 24, line 16 of the bill H. R. 13254, as reported; before the semicolon:

Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.

The bill, as amended, has the approval of the Department of Health, Education,

and Welfare, and of the organizations which represent the various industry groups which are affected by this legislation. The letter of the Department of Health, Education, and Welfare, endorsing the bill, as amended, reads as follows:

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
Washington, August 8, 1958.

FROM: OREN HARRIS,
Chairman, Committee on Interstate
and Foreign Commerce, House of
Representatives, Washington, D. C.

DEAR MR. CHAIRMAN: This is in reply to your letter of August 5, 1958, acknowledging our endorsement of H. R. 13254, the proposed Food Additives Amendment of 1958, which was reported favorably by our committee with an amendment (in the nature of a substitute) on July 28, 1958, and requesting an expression of our additional views on the bill in view of the amendments recommended by your committee.

The bill would require adequate testing of the safety of so-called intentional or incidental food additives, prior to their marketing and use, so as to establish their safety under the conditions of use to be specified by regulation. Present law, though restrictive as to use of known toxic substances in food, puts the burden on the Government to prove that the substance is a poisonous or deleterious substance. It may take two years or more of laboratory tests on animals to establish this, thus leaving the public without adequate protection in the meantime.

The bill covers those additives not generally recognized by competent experts as having been adequately shown to be safe under the conditions of their intended use. It covers substances that are added intentionally in foods as well as those that may reasonably be expected to become a component of food incidentally or to affect its characteristics. Irradiation of food would be covered by the amendment and would need to be established as safe before commercial use.

Substances commonly used in food before January 1, 1958, and generally recognized as safe because of experience based on such use, would be exempt from the law. Thus, sugar, salt, butter, lard, pepper, and numerous other ingredients would not have to go through the clearance procedures of the bill.

Substances that get into food wholly accidentally, such as paints, used in food processing plants, are not covered by the legislation. These accidental additives, if properly used, cannot reasonably be expected to become a part of food. If an accidental additive which is a poisonous or deleterious substance gets into food, the food would be deemed adulterated and dealt with under the basic 1938 law. The basic law allows no tolerance for such additives.

Other additives not covered by the new amendment are pesticide chemicals on raw agricultural commodities which are already taken care of under the Pesticide Chemicals Amendment (Public Law 518, 83d Cong.); residues of pesticide chemicals in processed foods which result from the proper use of raw materials that have legal pesticide residues; and substances that have already been approved for use in food, under the Food, Drug, and Cosmetic Act, or in the case of meats, under the Meat Inspection Act.

Briefly, the new law would work as follows with respect to additives within its scope:

1. A person who wants to promote a new food additive would have to test it for safety on animals and submit the results of the safety tests to the Food and Drug Administration of the Department of Health, Education, and Welfare.

2. Scientists of the Food and Drug Administration would study the safety data and

reach an independent decision as to the safety of the new ingredient for use in our food supply. If the data clearly demonstrate that the material could be safely used, under certain conditions of use, then this Department will, by order, issue a regulation stating safe permissible uses for the material. But if the safety of the additive is not reasonably certain, e. g., if the additive, in appropriate laboratory tests, indicates a potential of inducing cancer, the Department would not permit it and the public health would be safeguarded in a way that has not been possible heretofore.

3. The Department would not be permitted to sanction a use of an additive that promotes deception of consumers in violation of other provisions of the act or that otherwise would result in misbranding or adulteration of food within the meaning of the act. If the quantity of the additive to be used must be limited to safeguard health, then the Department could not allow any quantity in excess of the amount needed to accomplish the intended purpose, even if a greater amount would still be safe. Even the lower amount, of course, could not be allowed unless it is safe.

4. A person adversely affected by the Secretary's order would be entitled to a full administrative hearing on his objections. In case of actual controversy as to the Secretary's action after hearing, there would be a further opportunity for judicial review of the validity of the order on the basis of the record.

The Secretary's action after hearing would have to be based upon a fair evaluation of the entire record at the hearing. On judicial review, the United States Court of Appeals would be required to sustain the findings of the Secretary if based upon a "fair evaluation of the entire record at the hearing"; it would have to reverse the order of the Secretary if it is not "based upon a fair evaluation of the entire record" or if it fails to include a statement setting forth in detail the findings and conclusions upon which the order is based. The "fair evaluation" provision is quite acceptable to the Department, because it is the standard to which we are accustomed to adhere.

5. The amendment would become effective in three stages:

(a) The Department would be authorized to start making determinations as to the safety of a food additive when the law is enacted.

(b) The provisions of section 3 of the legislation (which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment in interstate commerce of an additive or food containing an additive, which has not been determined to be safe) would take effect 180 days after the enactment of the legislation. This is required because it will take a certain amount of time to make the necessary determinations of safety.

(c) With respect to any particular commercial use of a food additive which began before January 1, 1958, industry would be allowed 12 months after the effective date of section 3 (18 months after date of enactment) to present the necessary data to secure a regulation prescribing the conditions under which the additive may be safely used. This would permit an orderly transition from present procedures to those of the amendment. Where there would be no undue hazard to the public health and conditions necessitate further extension, the Secretary would have the authority to grant up to an additional 12 months for this clearance of old additive uses.

This is what is commonly referred to as the "grandfather clause" of the legislation but it is not a grandfather clause as that term is generally used. The grandfather clause, as proposed in some of the bills before your committee would have exempted

substances used in food prior to enactment of the legislation from having to meet its requirements at all. This Department opposed such a provision because prior use in food would not be an adequate substitute for a showing of safety.

In lieu of such a grandfather clause, the present legislation, as indicated above, prescribes a reasonable transition period which will guarantee prompt decision on the status of additives already in use in food and will grant industry a reasonable period of time in which to compile the data it has on the safety of the additives and if necessary to perform additional tests.

If the proposed legislation is not enacted, substances of unknown toxicity, which would be granted a limited time in which to meet the safety provisions of H. R. 13254, may continue to be used indefinitely and additional additives may be marketed for use in food without any requirement that their safety first be established. So a reasonable choice is not between allowing the old additives or not allowing them. The choice is between establishing their safety as soon as is practical under the transition period allowed in H. R. 13254 or allowing their continued use without any requirement that their safety be reevaluated. However, the transitional period does not protect additives whose toxicity is known and which are barred under present law. Food containing such additives could meanwhile be proceeded against under present law.

We would like, also, to make special mention of: (1) The advisory committee procedure; (2) the cancer question; and (3) the functional value question.

1. The advisory committee procedure was incorporated in the proposed legislation which this Department submitted to Congress (H. R. 6747) to give industry an opportunity to have petitions reviewed by a panel of outside scientists. We do not object to the committee's deletion of the procedure, because the Department already has the privilege of making inquiry of competent outside scientists on technical matters.

2. The widespread interest in cancer led to suggestions that the food additives legislation should mention the disease by name and forbid the approval of any substance that is found upon test to cause cancer in test animals. This Department is in complete accord with the intent of these suggestions—that no substance should be sanctioned for uses in food that might produce cancer in man. H. R. 13254, as approved by your committee, will accomplish this intent, since it specifically instructs the Secretary not to issue a regulation permitting use of an additive in food if a fair evaluation of the data before the Secretary fails to establish that the proposed use of the additive will be safe. The scientific tests that are adequate to establish the safety of an additive will give information about the tendency of an additive to produce cancer when it is present in food. Any indication that the additive may thus be carcinogenic would, under the terms of the bill, restrain the Secretary from approving the proposed use of the additive unless and until further testing shows to the point of reasonable certainty that the additive would not produce cancer and thus would be safe under the proposed conditions of use. This would afford good, strong public health protection.

There are many serious conditions other than cancer that may be caused or aggravated by the improper use of chemicals. It is manifestly impracticable to itemize all of them in a bill. To single out one class of diseases for special mention would be anomalous and could be misinterpreted. Hence, in drafting the Department's bill (H. R. 6747) we chose general language that would restrain any use of an additive that would have any adverse effect on the public health.

This approach has been followed in H. R. 13254.

At the same time, if it would serve to allay any lingering apprehension on the part of those who desire an explicit statutory mandate on this point, the Department would interpose no objection to appropriate mention of cancer in food additives legislation. If the specific disease were referred to in the law, it would however, be important for everyone to have a clear understanding that this would in no way restrict the Department's freedom in guarding against other harmful effects from food additives.

It would be important, also, to use language that would provide the intended safeguards without creating unintended and unnecessary complications. For example, the language suggested by some to bar carcinogenic additives would, if read literally, forbid the approval for use in food of any substance that causes any type of cancer in any test animal by any route of administration. This could lead to undesirable results which obviously were not intended by those who suggested the language. Concentrated sugar solution, lard, certain edible vegetable oils, and even cold water have been reported to cause a type of cancer at the site of injection when injected repeatedly by hypodermic needle into the same spot in a test animal. But scientists have not suggested that these same substances cause cancer when swallowed by mouth.

The enactment of a law which would seem to bar such common materials from the diet on the basis of the evidence described above, would place the agency that administered it in an untenable position. The agency would either have to try to enforce the law literally so as to keep these items out of the diet—evidently an impossible task—or it would have to read between the lines of the law an intent which would make the law workable, without a clear guide from Congress as to what was meant.

This difficulty could readily be avoided, if there is still a desire to make specific mention of cancer in the bill, by providing that "no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in animals." Such language could be appropriately inserted as a proviso before the semicolon on page 24, line 16, of the bill as reported by your committee.

3. The functional value provision of this Department's bill (H. R. 6747) was proposed to prevent the useless addition of toxic chemicals to food, to prevent the use of more of an additive which requires limitation in the interest of safety than is needed to accomplish the intended benefit, and to prevent deception of the consumer. Some objected to this provision as it appeared in H. R. 6747, in the belief that it would require this Department, in some respects, to make subjective judgments on questions not readily resolved on a factual basis. H. R. 13254 is, clearly, not open to this objection but it retains the essential consumer protection features that were to be accomplished by the functional value provision in the following manner:

(a) If the additive requires a tolerance limitation to insure its safe use:

(1) The Secretary may permit the proposed use only if the data before him show that it would accomplish the intended physical or other technical effect. This would prevent the useless additional toxic chemicals to food.

(2) The Secretary would only fix the tolerance limitation at the level reasonably required to accomplish the physical or other technical effect (provided, of course, this level is safe). This would prevent the use of more of a toxic chemical than is needed to accomplish the intended effect.

(b) The Secretary would be forbidden to permit use of an additive if the data before him showed that the proposed use would promote deception of the consumer in violation of, or would otherwise result in adulteration or misbranding within the meaning of the Federal Food, Drug, and Cosmetic Act.

In conclusion, we strongly urge the enactment of the bill by the present Congress in order to close a serious gap in the present law.

In view of the urgency of this report, time has not permitted its submission to the Bureau of the Budget for advice in accordance with the usual procedure.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary.

Great credit is due the chairman and the members of the Subcommittee on Health and Science who worked so conscientiously to bring about substantially unanimous agreement with regard to this legislation which has been in the making for 6 years.

Instead of attempting to explain the bill, as amended, section by section, I feel that it would be easier to present an analysis of the principal provisions of this legislation.

SUBSTANCES COVERED BY LEGISLATION

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (including a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

REGULATION TO ESTABLISH SAFETY

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of a petition filed by any person (ordinarily the manufacturer of the additive) or on the Secretary's own initiative.

The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practical methods to determine the quantity of such additive left in or on food because of its use.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

CONCEPT OF SAFETY

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the ab-

solute harmlessness of any chemical substance.

In determining the safety of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under like patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm, and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) The probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

GROUND FOR DENIAL OF PETITION

The Secretary would deny a petition to establish the safety of an additive if the data before the Secretary fail to establish that the proposed use of the additive under the specified conditions of use will be safe.

The Secretary could also deny a petition on the ground that the proposed use of the additive would promote deception of the consumer in violation of the Food and Drug Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Food and Drug Act.

TOLERANCE LIMITATIONS

In the case of an additive which in the judgment of the Secretary based upon a fair evaluation of the data before him, requires a tolerance limitation in order to assure that the proposed use of such additive will be safe, the legislation establishes two standards:

First, the Secretary may not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

Second. The Secretary may not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

The phrase "physical or other technical effect" refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food. The question of whether an additive produces such effect—or how much of an additive is required for such effect—is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added value to the consumer of such food or enhances the marketability from a merchandising point of view.

ADVISORY COMMITTEES

The committee has deleted the advisory committee procedure from the bill because there does not appear to be any need for this complicated mechanism for securing the views of scientists. The Department already has the privilege of making inquiry of competent outside scientists on technical matters.

PUBLIC HEARINGS

Any person adversely affected by an order of the Secretary may file objections thereto and request a public hearing. At such hearings the Secretary would receive evidence relevant and material to the issues raised and would by order act upon such objections.

JUDICIAL REVIEW

The committee has given long and careful thought to the problem of the scope of judicial review under this legislation. This problem was discussed exhaustively by several witnesses, including a Federal judge who testified on behalf of the Judicial Conference of the United States.

The committee feels that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial without taking account of contradictory evidence of possible equal or even greater substance.

In the course of the scientific panel hearings, the subcommittee was impressed with the wide range of scientific judgment factors which are involved in determining the safety of a food additive. Considering the eminent qualifications of all the scientists and experts who participated in these panel hearings, the scientific testimony of any one of the participants must be considered substantial evidence. Nevertheless, any conclusions based solely on the scientific judgment of any one of the participants without taking account of contradictory scientific views expressed by other participants cannot be considered conclusions based upon a fair evaluation of the entire record.

Thus, under this legislation, the Secretary's findings of fact and orders based thereon must be based upon a fair evaluation of the entire record. The committee adopted the language, "fair evaluation of the entire record" because it seemed to express most clearly the standard of judicial review of administrative findings of fact and orders based thereon which the committee feels should prevail.

The bill provides that the reviewing court shall not sustain the order of the Secretary if he failed to base such order upon a fair evaluation of the entire record at such hearing, or if he failed to include in such order a statement setting forth in detail the findings and conclusions upon which the order is based. The court must sustain the findings of the Secretary with respect to questions of fact if based upon a fair evaluation of the entire record.

Judicial review of any order of the Secretary under this legislation may be obtained in the United States court of appeals for the circuit wherein appellant resides, or has his principal place of business, or in the United States Court of Appeals for the District of Columbia.

EFFECTIVE DATE

This legislation will, except as herein-after stated, take effect on the date on which it is enacted. Thus the Food and Drug Administration can immediately begin making determinations as to the safety of food additives.

However, since it will take a certain amount of time to make these determinations of safety, the provisions of section 3 of the legislation—which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment in interstate commerce of an additive, or food containing an additive, which has not been determined to be safe—will not take effect until 180 days after the enactment of this legislation.

A further exception is made in the case of any particular commercial use of a food additive if such use began before January 1, 1958. In the case of such use, section 3 would take effect either on the establishment of an order with respect to the safety of such use, or 18 months after the date of enactment of the legislation—unless extended by the Secretary for not more than an additional 12 months—whichever date occurs first.

MEAT INSPECTION

The bill as amended provides that nothing in this legislation shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907. This provision would leave unaffected the jurisdiction of the Department of Agriculture with respect to food additives in establishments which are subject to the Meat Inspection Act.

(Mr. HARRIS asked and was given permission to revise and extend his remarks.)

Mr. HARRIS. I ask unanimous consent at this point to include in the Record a statement from the gentleman from Mississippi [Mr. WILLIAMS], chair-

man of the subcommittee, who worked so faithfully on this legislation.

The SPEAKER. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

Mr. WILLIAMS of Mississippi. Mr. Speaker, H. R. 13254, with the amendments recommended by the Committee on Interstate and Foreign Commerce, will provide protection for the consuming public by requiring that only safe chemically produced substances be added to food. The clean, tasty, and wholesome packages of prepared foods which are bought in the grocery store today could not exist without the scientific advances which have been made in the field of food chemistry. The Federal pure food law needs to be amended primarily because of the continuing progress in food technology. The progress which has been made in this field during the last 10 or 15 years has liberated American women from much of the drudgery of the kitchen.

The last major revision of the Food and Drug Act occurred 20 years ago. The 1938 law was designed primarily to protect our national food supply by preventing the inclusion in food of filth and foreign matter and by prohibiting the addition of substances which conceal defects such as spoilage or deterioration of food. The 1938 law gave no recognition to substances deliberately added to food for beneficial purposes, such as retarding natural spoilage or keeping food moist or tasty. There is a gap in our pure food law as a result of advancing technology.

The substances dealt with by this bill are unfamiliar to many of us because they are referred to as chemical additives. All foods are composed of ingredients which can be identified by chemical nomenclature. Many food additives are produced or refined by chemical processes and can be identified by chemical names. Table salt, or sodium chloride as it is known chemically, is one of the oldest food additives. Another food additive is baking soda, or sodium bicarbonate. Vitamins, which are produced principally by chemical processes, have complicated scientific names. Citric acid, which nature produces in lemons, oranges, and limes, is produced in commercial quantities from sugar. Whether derived from lemons or limes or from a process of fermenting sugar, when citric acid is added to a soft drink to improve the taste or used in some other food or beverage, it would be classed as a "food additive" under this bill. It has been a common practice in recent years for bakeries to add a tiny amount of sodium propionate to bread and other bakery products to keep them fresh and tasty for longer periods than would be possible without the additive. These and the many other substances which are used to improve the characteristics of our food are illustrative of the kinds of things this legislation deals with.

The Food and Drug law of 20 years ago, under which we still operate today, was not written to deal with the food

technology of today. This bill is needed to bring the 1938 law up to date.

H. R. 13254 would require manufacturers of food additives and processors of food products to make careful advance tests of any substance which is to be added to food or any substance which, if used in the manufacture of food products, can reasonably be expected to become a part of the food. The required testing involves the most searching analysis by pharmacologists and other scientists as to whether the proposed food additive would have any harmful effect upon those who eat the food containing it. Adequate scientific testing of this sort usually takes 2 years or longer. The manufacturer or processor must maintain detailed records of his tests and the results. H. R. 13254 requires that the complete test data be submitted to the Food and Drug Administration for thorough review. If the Food and Drug Administration is satisfied that the scientific tests of the new additive prove it can be used safely in the quantity and under the circumstances proposed by the manufacturer, the Secretary of Health, Education, and Welfare will issue a regulation describing precisely the conditions under which the product can be used. After the enactment of this bill food additives cannot be placed on the market in interstate commerce unless these requirements are fully complied with.

The subcommittee and the full committee had two major objectives in writing this legislation. First and foremost, we wanted to insure that the public would be adequately protected. Secondly, we wanted to establish a high standard of administrative fairness.

In our hearings we received testimony from Government officials and representatives of the affected industries. At our request, the National Academy of Sciences appointed a panel of highly qualified scientists, who appeared before the subcommittee and discussed the questions of safety which are involved in the use of food additives.

As pointed out in the committee report, the bill uses a concept of safety which involves the question of whether the use of a substance in food would be hazardous to the health of man or animal. To establish the safety of an additive the bill requires proof of the practical certainty that no harm will result from the proposed use of the substance. The bill does not—and cannot—require proof beyond any possible doubt that no harm could result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee.

In determining the safety of an additive, the Secretary of Health, Education, and Welfare would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of

additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer-causing characteristics of a proposed additive, the public will be protected from possible harm on this count. A committee amendment to the bill expressly indicates that any substance found to cause cancer cannot be approved.

The bill covers substances which are intentionally added to food. It also covers substances which may reasonably be expected to become a component of food or to affect the characteristics of any food. On the other hand, it does not cover substances which may accidentally get into food. These latter would be dealt with by other provisions of the Food, Drug, and Cosmetic Act.

I have been asked since the Committee reported the bill what is meant by a substance "holding" food, as mentioned in the bill. An example of what is meant by this would be a plastic film or paper wrapper which surrounds a package of food. This bill is not intended, for example, to give the Food and Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils.

Another question I have been asked is why H. R. 13254 does not contain a provision of the type in H. R. 6747 which brought "food additive" within the meaning of the term "food."

It was the feeling of the Committee that such a provision would be surplusage since the present Food and Drug law, in section 201 (f), already defines "food" as including all components thereof. Since substances which get into food incidentally in its manufacture, handling, or packaging would be dealt with as a "food additive" under the bill, there appears to be no need to have such substances also defined as a "food."

The bill does not duplicate the provisions of law which already control the use of pesticide chemicals on growing crops or raw agricultural commodities.

Ever since the Congress began delegating regulatory functions to administrative agencies of the Government there has been disagreement among lawyers as to the fairness of the procedures under which the agencies operate. In 1946, the Administrative Procedure Act was passed in an effort to formalize the day-to-day rule making and regulatory procedures of Government agencies. The 1946 act provides that unless the findings of fact upon which administrative orders are based are supported by "substantial evidence" a Federal Court of Appeals can reverse the order of the administrative agency. Court decisions have required that an administrative agency must give consideration to the entire record, including contradictory evidence, when it determines facts.

Manufacturers of food and of food additives have manifested concern that under an administrative type of control

over the use of food additives, such as is provided by H. R. 13254, it would be possible for the institutional decisions of the Secretary of Health, Education, and Welfare to be based, for example, more upon the personal convictions of scientists employed by the Food and Drug Administration regarding the safety of an additive than upon the inferences fairly to be drawn from the scientific evidence of record. H. R. 13254 provides that orders regarding the use of food additives must "be based upon a fair evaluation of the entire record." The committee has endeavored to prescribe a new statutory criterion requiring that a high standard of fairness be observed in administrative rulemaking under this bill. Personal attitudes or preferences of administrative officials could not prevail on the basis of being supported by substantial evidence picked from the record without regard to other evidence of probative value in the record. The United States Courts of Appeals will be able to enforce this high standard by determining whether the Secretary of Health, Education, and Welfare has given appropriate consideration to the inferences which should fairly be drawn from all of the evidence of record.

I want to point out that this bill has the unqualified support of the Department of Health, Education, and Welfare as well as the officials of the Food and Drug Administration who would be charged with responsibility for administering the law. They are satisfied that this bill would provide fully adequate protection for consumers.

A substantial majority of the manufacturers of food products have unqualifiedly approved this bill, as have a majority of the manufacturers of food additives.

It has taken several years for the Government agencies and the affected industries to agree upon a bill, and I hope H. R. 13254 will be passed by the House and be enacted into law before the present session adjourns.

Mr. O'HARA of Minnesota: Mr. Speaker, I yield such time as he may desire to the gentleman from Virginia [Mr. POFF].

Mr. POFF. Mr. Speaker, I am in favor of the bill.

Mr. Speaker, I applaud and commend the chairman and members of the Committee on Interstate and Foreign Commerce for their work and the results of their work on H. R. 13254 to amend the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety for human consumption.

As I understand the bill, pretesting of additives is required only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures or, in the case of substances in use prior to January 1, 1958, by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as intentional additives.

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as incidental additives.

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of petition filed by any person—ordinarily the manufacturer of the additive—or the Secretary's own initiative. The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practical methods to determine the quantity of such additive left in or on food because of its use.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the safety of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together

with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: First, the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; second, the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and third, safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer-causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

The Secretary would deny a petition to establish the safety of an additive if the data before the Secretary fails to establish that the proposed use of the additive under the specified conditions of use will be safe.

The Secretary could also deny a petition on the ground that the proposed use of the additive would promote deception of the consumer in violation of the Food and Drug Act or would otherwise result in adulteration or is misbranding of food within the meaning of the Food and Drug Act.

In the case of an additive which in the judgment of the Secretary based upon a fair evaluation of the data before him, requires a tolerance limitation in order to assure that the proposed use of such additive will be safe, the legislation establishes two standards:

First. The Secretary may not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended.

Second. The Secretary may not establish a regulation for such proposed use

if he finds upon a fair evaluation of the data before him that such data does not establish that such use would accomplish the intended physical or other technical effect.

The phrase "physical or other technical effect" refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food. The question of whether an additive produces such effect—or how much of an additive is required for such effect—is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added value to the consumer of such food or enhances the marketability from a merchandising point of view.

Any person adversely effected by an order of the Secretary may file objections thereto and request a public hearing. At such hearings the Secretary would receive evidence relevant and material to the issues raised and would by order act upon such objections. From the final decision of the Secretary an appeal could be taken to the courts.

This legislation is in the public interest and should become public law at this session of Congress.

(Mr. POFF asked and was given permission to revise and extend his remarks.)

Mr. O'HARA of Minnesota. Mr. Speaker, I yield 3 minutes to the gentleman from Nebraska [Mr. MILLER].

(Mr. MILLER of Nebraska asked and was given permission to revise and extend his remarks.)

Mr. MILLER of Nebraska. Mr. Speaker, I had the privilege of serving on the Delaney committee in 1951 when we investigated rather carefully and had extensive hearings on the use of chemical additives in food.

In the 83d Congress we passed a bill known as the pesticide bill, which deals with the use of pesticides in the production of food. That bill is working very nicely now. It was a byproduct of the so-called Delaney Committee on Food Additives and Pesticides.

However, there is one thing I would have had in this bill, and I also testified before the committee on several occasions pointing out what I thought ought to be in a good food additives bill.

We had placed in the insecticide bill a provision for an expert council. In other words, when industry and the administration disagree, either one may ask for a panel of experts to adjudicate, or at least to have hearings on their differences. This was advisory only, but it was an intermediate step which permitted them to bring their grievances before an expert committee. Then they had the right after that to go to court, as they have in this bill, but the intermediate step was an advisory committee of some kind that we had in the insecticide bill. It is working in connection with the bill that was passed in the 83d Congress, and I had hoped this bill would contain the same provision because it is an escape valve. Otherwise the Department takes weeks and months; and, as was the case in the bread hearings, nearly 2 years to determine whether additives should be placed in the bread.

While this council is only advisory in nature, the court takes into consideration the findings of the experts on the council.

Although it is not in this bill, I am for it; I think it is a step forward, it is a step that will protect the consuming public and will give more confidence in the use of some food, because in our economic world as it exists today there is a chance for people who are not as scrupulous and as careful as they should be to cut corners. We do have under the present law people putting chemicals into foods before they are adequately tested. This calls for a pre-testing and determination by the Food and Drug Administration of the Department as to whether the chemical additives are needed and are a help to any particular food.

(Mr. MILLER of Nebraska asked and was given permission to revise and extend his remarks.)

Mr. HARRIS. Mr. Speaker, I am delighted to yield 5 minutes to the gentleman from New York [Mr. DELANEY].

(Mr. DELANEY asked and was given permission to revise and extend his remarks.)

Mr. DELANEY. Mr. Speaker, regulation of the use of chemical additives in our food supply is one of the most important domestic issues to be considered by the Congress, and for this reason I regret that this bill was reported so late in the session.

The safeguarding of the health of the American public should ever be uppermost in our minds. In these fast moving times, food technology changes almost from day to day and it is difficult to keep up with developments.

Recognizing the problems created by the increasingly widespread use of chemical additives, in 1950 the House authorized the formation of a select committee to investigate the use of chemicals in foods and cosmetics, and I had the honor to be chairman. Many of you are familiar with that investigation, and it should be enough to recall that the committee held extensive hearings in various parts of the country in 1950, 1951, and 1952, and heard testimony from qualified experts only. The investigation established beyond question that legislation is absolutely necessary in this field to insure the public of a full measure of protection.

Here I should like to pause to pay tribute to my former committee colleagues. The devotion with which they carried out their task was notable, and they gave unstintingly of their time and effort.

As a result of this investigation, in 1953 I introduced the first chemical additive bill. No action resulted. Again in the 84th Congress I introduced a similar bill. Hearings were held on that and several industry bills, but nothing was reported out of committee. In January of last year I introduced H. R. 4014, which was superseded a few months later by H. R. 7798. This latter bill contained a provision which would prohibit the use of any cancer-inducing chemical additive in food.

This particular provision followed the recommendation of the International Union Against Cancer at its cancer symposium held in Rome in August 1956. At that time, the members of the conference, consisting of over 40 cancer experts from some 21 countries, unanimously recommended that as a basis for active cancer prevention, the proper authorities of various countries promulgate and enact adequate rules and regulations prohibiting the addition to food of substances found to be cancer inducing.

I discussed this recommendation with such eminent American cancer researchers as Dr. William E. Smith, executive secretary of the cancer prevention committee of the International Union Against Cancer; Dr. W. C. Hueper, of the National Cancer Institute; and Dr. Francis E. Ray, director of the cancer research laboratory of the University of Florida; also with Dr. W. Coda Martin, president of the American Academy of Nutrition. All of them strongly supported the position of the International Union.

So far as medicine is concerned, I make no pretense to any special knowledge. I felt that the recommendation of so many experts, both in countries abroad as well as in the United States, should not be disregarded. Accordingly, I amended H. R. 4014 to include an anti-carcinogen provision, and introduced H. R. 7798.

Another reason for this action was that I found that for 2 years a residue of a chemical pesticide known to induce cancer in animals has been permitted to remain on many raw agricultural commodities. I brought this to the attention of the House on several occasions. FDA is now acting to bar this pesticide. It use should never have been permitted in the first place. I felt strongly that the public should be assured that no similar incident would occur with regard to food additives.

Mr. Speaker, when the committee bill, H. R. 13254, was reported, I was deeply disappointed to find that it did not contain a specific carcinogen prohibition.

I made my concern known, and I am pleased to say that last week, after prolonged consultation with representatives of the Food and Drug Administration, we were able to work out a carcinogen amendment acceptable to the committee. If this bill, with the amendment, passes the House today and should by any chance later go to conference, I have been assured that the House conferees will insist on retaining the amendment.

With this amendment, and with this assurance, I shall vote in support of H. R. 13254.

Mr. Speaker, at this point I ask unanimous consent to include a letter from the Food and Drug Administration, the Agency will have the responsibility of enforcing this legislation. This letter is under the signature of Mr. John L. Harvey, the Deputy Commissioner, and it clarifies some of the important points I raised.

The SPEAKER. Is there objection to the request of the gentleman from New York?

There was no objection.

The letter reads as follows:

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D. C., August 7, 1958.
HON. JAMES J. DELANEY,
House of Representatives
Washington, D. C.

DEAR MR. DELANEY: This confirms my telephone conversation on August 6 with your office about H. R. 13254. In accordance with your request, we are enclosing 4 copies of the language we discussed which, if inserted into H. R. 13254, would show in the law itself that no substance is to be approved for use in food if it causes cancer when eaten by man or test animals.

As you know, section 6 of H. R. 13254 would have the food additives amendment become effective on the same time schedule as was provided in section 7 of H. R. 6747. (There has been some change in language which was made by the legislative draftsmen of the House but the effect remains the same.) This has sometimes been referred to as a grandfather clause but it is not really a grandfather clause as that term is ordinarily used. The grandfather clause in some of the bills sponsored by industry would have exempted substances used in food prior to enactment of the legislation from having to meet its requirements at all.

In lieu of that, the Department's bill, and the committee's redraft of it, prescribe a reasonable transition period which will guarantee prompt decision on the status of additives already in use in food. We doubt if it would be practical to have the law become fully effective without some such transition period to permit the status of additives already in use to be established. This transition period would not allow continued use of substances known to be harmful; it would apply to substances that are not known to have any harmful effect.

Another provision of H. R. 13254 that has sometimes been regarded as a grandfather clause is the one that would exempt from the definition of food additive substances used in food prior to January 1, 1958, that have been adequately shown through experience based on common use in food to be safe under the conditions of intended use. Our Department believes that it is not necessary to good public health protection to have chronic toxicity studies conducted of common food chemicals, such as salt, sugar, vinegar, baking soda, and a great many other materials that have been in common use for a long time. As a matter of fact, these substances have been established as suitable food ingredients through feeding to generations of human beings. Further, if the legislation required such common chemicals to be subjected to chronic toxicity tests on animals, there would not be enough laboratory facilities in the country to handle the testing job within a period of several years.

But this is not a grandfather clause either. If later developments show that a substance previously considered safe because of common use in food were, in fact, subject to question and not generally recognized as safe, then the substance would become subject to the definition of a food additive and would have to be cleared under the procedures of the proposed law. For example:

1. Coumarin was used as an ingredient of imitation vanilla flavor for 75 years, but a few years ago, tests indicated that it caused adverse effect when fed to test animals in dosages considerably higher than the quantities present in man's diet. In our view,

had H. R. 13254 been law, coumarin would automatically have been subject to its provisions when the animal test data became available.

2. Dulcin is an artificial sweetener that was used to some extent for about 50 years until tests in our laboratories showed that it is capable of causing harm. Had H. R. 13254 been law, such a showing would automatically have brought the production within its coverage.

3. Nitrogen trichloride (Agene) was in common use in this country as a flour bleach until experiments in England and the United States showed in the 1940's that flour treated with it is capable of causing running fits in dogs. Under the terms of H. R. 13254, such a showing would automatically have brought the compound under the definition of a food additive and made it subject to the clearance procedures of the bill.

You asked for an explanation of the manner in which H. R. 13254, would permit the Department to control residues in meat, milk, eggs, and similar products when the residues are not added directly to the food but occur because of some chemical that is present in animal feed.

We believe control of this type of residue is adequately covered in lines 13 through 15 on page 25 of H. R. 13254. This language would permit the Secretary, in determining whether a proposed use of an additive is safe, to consider the probable consumption of the additive and of any substance formed in or on food because of the use of the additive. We believe that the intent of your bill, H. R. 7798, is preserved by this language. Our view is supported by the language of report No. 2284 of the Interstate and Foreign Commerce Committee on H. R. 13254 which states: "In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods."

H. R. 13254 provides that when the Secretary issues an order following a public hearing and the order is reviewed by a circuit court of appeals, the findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. This in our view is the substantial evidence rule already present in the Food, Drug, and Cosmetic Act as it has been interpreted by the Supreme Court in *Universal Camera Corporation v. National Labor Relations Board* (340 U. S. 474, 1950). The Supreme Court held "that a reviewing court is not barred from settling aside an agency's decision when it cannot conscientiously find that the evidence supporting that decision is substantial, when viewed in the light that the record in its entirety furnished." The Supreme Court also held that the agency's findings must be set aside when the record before a court of appeals clearly precludes the agency's decision from being justified by a fair estimate of the worth of the testimony.

We believe H. R. 13254 as reported by the House Committee on Interstate and Foreign Commerce, is clearly enforceable and gives the sound public health protection that is required.

Sincerely yours,

JOHN L. HARVEY,
Deputy Commissioner.

Mr. DELANEY. Mr. Speaker, I call particular attention to the concluding sentence:

We believe H. R. 13254 * * * is clearly enforceable and gives the sound public-health protection that is required.

I have been assured that there is no grandfather's clause which would have the effect of exempting the more than 150 additives now in use that the experts

feel have been insufficiently tested. Other questions are covered by this letter and the committee report.

Mr. Speaker, I know from experience how difficult it is to legislate on a subject as complex and broad in scope as this one. In this scientific field the great majority of us are laymen, and I appreciate the time and effort the members of the Subcommittee on Health and Science devoted to acquainting themselves with it. I also appreciate the pressures to which they were exposed. I feel they are to be commended in bringing chemical additive legislation to the floor.

I do not consider H. R. 13254 an ideal bill. I would have preferred a more direct approach to certain problems and clearer language. However, it is a definite step forward, and I am convinced that if the bill is not passed we will have no chemical additive legislation for some time to come, and the public will be deprived of much needed protection.

If this bill is passed—and I hope it will be—the book on chemical additives is not necessarily closed. We must watch the effect of this legislation closely and, if it does not afford the health protection its proponents hope for, we must stand ready to make the necessary amendments.

In concluding my remarks I should like to thank the many, many thousands of people who have written me from all over the country. Their support of my efforts to secure the enactment of protective chemical additive legislation has been a real inspiration to me and I know that their interest has helped to bring about action.

Mr. Speaker, I urge the adoption of the bill with the amendment.

Mr. FOGARTY. Mr. Speaker, will the gentleman yield?

Mr. DELANEY. I yield to the gentleman from Rhode Island.

Mr. FOGARTY. I would just like to compliment the gentleman from New York for the long and arduous task that he has been performing in holding hearings on this most important subject and to agree with him that this is one of the most important bills that will pass the Congress this year for the protection of the people of this country. Now, the gentleman spoke of enforcement by the Food and Drug Administration. How many additional positions do you think it will take to carry out the provisions of the bill or the wishes of this committee?

Mr. DELANEY. I am notified by Food and Drug that it will require very few. They have a staff. Of course, they could use a great number of other experts, but they can, without any great number of additional jobs, carry out the enforcement provisions.

Mr. FOGARTY. There are many people today who believe that the Food and Drug Administration ought to be expanded without any additional legislation, and I was wondering how that feeling fits in with the expressed views of you and your committee on this bill.

Mr. DELANEY. Food and Drug has assured me that if this bill is passed, they can adequately protect the health of the American public.

Mr. HARRIS. Mr. Speaker, I yield to the gentlewoman from Missouri [Mrs. SULLIVAN].

Mrs. SULLIVAN. Mr. Speaker, would the chairman of the committee yield for a question? With the very limited time allotted for debate on this bill, I do not want to attempt to go into any detail on it. I know there is not time. As one of the longtime sponsors of legislation on this subject, however, I do have some things I want to get into the RECORD on it, and I am going to seek permission to have my remarks included. I do not think this is a strong bill. But as the remarks I have prepared will point out, it can accomplish a great deal more than the existing law, and I will support it. But one aspect that I think should be brought out in the debate—one that I think is very important—is this:

Am I correct that while the bill primarily deals with new chemical additives, it does not preclude the Food and Drug Administration from moving against existing additives if they have evidence to question their safety?

Mr. HARRIS. Yes; I will say that the gentlewoman is correct in her statement.

Mrs. SULLIVAN. I thank the gentleman.

(Mrs. SULLIVAN asked and was given permission to revise and extend her remarks and also to extend her remarks at the close of debate on the bill.)

Mr. HARRIS. Mr. Speaker, I yield such time as he may require to the gentleman from Michigan [Mr. DINGELL], a member of the committee.

Mr. DINGELL. Mr. Speaker, I thank the distinguished chairman of the committee for this opportunity to speak on this particularly important piece of legislation.

Mr. Speaker, my reason for rising at this time was to pay tribute to the Committee on Interstate and Foreign Commerce for the splendid job they have done in bringing this bill before the House. I did not want to let this opportunity pass without also paying tribute to the distinguished gentleman from New York [Mr. DELANEY] for his help and assistance to the committee in bringing this piece of legislation to the floor. I am sure that every Member of this House of Representatives will be well satisfied with the product of today's work on this particular bill since this bill for the first time offers real and complete protection to the American people so far as additives to foods are concerned.

(Mr. DINGELL asked and was given permission to revise and extend his remarks.)

Mr. O'HARA of Minnesota. Mr. Speaker, I yield such time as he may require to the gentleman from Washington [Mr. TOLLEFSON].

Mr. TOLLEFSON. Mr. Speaker, I want to commend the committee for giving study to the subject matter of this bill and for bringing the bill to the floor. As several speakers have already said, this is a step in the right direction. A great many people in my congressional district have written to me expressing their concern over the problem with which the bill seeks to deal.

I trust that the House will approve the bill.

(Mr. TOLLEFSON asked and was given permission to revise and extend his remarks.)

Mr. O'HARA of Minnesota. Mr. Speaker, I yield myself 1 minute, and I yield to the gentleman from Nebraska [Mr. MILLER].

Mr. MILLER of Nebraska. Mr. Speaker, I wanted to ask the chairman of the committee about this carcinogenic amendment. I do not find it in the bill. Is it to be offered as a committee amendment?

Mr. HARRIS. I will say to the distinguished gentleman that it is offered as a committee amendment.

Mr. MILLER of Nebraska. I have not seen the amendment yet.

Mr. HARRIS. I should be glad to read it, if the gentleman wishes.

Mr. MILLER of Nebraska. I think it is a rather unusual amendment to be offered in a bill of this type. Does the gentleman include cigarettes, which we know are carcinogenic?

Mr. HARRIS. I should be glad to read the amendment. It is at page 24, line 16, as follows:

Page 24, line 16, before the semicolon insert the following: "Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."

Mr. MILLER of Nebraska. If the gentleman will yield further, it seems to me that no one would object to an amendment which has for its purpose to prevent cancer. But it certainly has no place in this bill, because it would be impossible to administer. I should think the Food and Drug Administration would be very much opposed to it. If we are going to have this kind of amendment, then we ought to include cigarettes, which we know are a cause of cancer of the lungs.

Mr. HARRIS. I would say to the gentleman that the Food and Drug Administration has no objection to this amendment.

Mr. MILLER of Nebraska. I am sure they will not do anything about enforcing it, because it is impossible to enforce; that is, to determine what foods, if any, would produce any carcinogenic tendencies in human beings.

Mr. HARRIS. That is the gentleman's conclusion. I am sure if there is any difficulty with this amendment, realizing the importance of it in connection with the administration of it, we will be requested by the Food and Drug Administration to make further clarification.

Mr. O'HARA of Minnesota. Mr. Speaker, I yield myself 5 minutes.

Mr. Speaker, I have had a good deal of interest in the subject of legislation pertaining to chemical additives. As a matter of fact, over the last four Congresses I have introduced bills pertaining to this subject, which were suggested by some of the finest food manufacturers in the country. They have been concerned about it themselves. In the 83d and 84th Congresses the late Percy Priest, for-

mer chairman of our committee, and I, were authors of companion bills dealing with this subject.

This bill is helpful in the problem of dealing with chemical additives in food. There have been a great deal of hysteria stirred up by some people on this subject. I think the bill could have been much worse than it is and I think it could have been a better bill. I am supporting it, but I do not want to hold it out as being the answer to everything that some might think it would be.

Mr. DINGELL. Mr. Speaker, will the gentleman yield?

Mr. O'HARA of Minnesota. I yield to the gentleman from Michigan.

Mr. DINGELL. I should like to clarify one thing a Member on that side of the aisle said a moment ago. The gentleman from Nebraska [Mr. MILLER] said that the feature dealing with carcinoma in this bill is impossible to administer. I am very much surprised to have a medical doctor make a statement like that. That particular amendment not only has the approval of the Food and Drug Administration but it was offered to them for their approval and it has their full and express approval.

We know enough now about cancer-producing substances to know at this particular time that there are substances that will produce cancer within the bodies of test animals and of human beings.

Mr. O'HARA of Minnesota. I should like to yield further to the gentleman but first I want to finish my statement.

Mr. DINGELL. I hope the gentleman will yield to me later.

Mr. O'HARA of Minnesota. I am sure the gentleman on the other side will yield some time to the gentleman from Michigan.

Mr. MILLER of Nebraska. Mr. Speaker, will the gentleman yield?

Mr. O'HARA of Minnesota. I yield.

Mr. MILLER of Nebraska. May I say to the gentleman that if he has any evidence of any food or anything else that causes a carcinogenic condition in human beings he ought to get that evidence before the Food and Drug Administration. We had no evidence before our committee that any foods had carcinogenic tendencies. Certainly we know something about cigarettes being carcinogenic. This amendment will not prove anything about whether in the gentleman or me or anybody else it would cause cancer.

Mr. O'HARA of Minnesota. Our subcommittee had before it a distinguished panel of the outstanding cancer experts of the United States. Certainly they did not go as far as some of the statements made here, or in the newspapers, as to what was a cancer-producing food. Personally I agree with the gentleman from Nebraska that this is an unfortunate amendment. I voted against it in the committee when it was offered. I do not think it has any place in this bill. However, it was adopted by a majority of the committee, and of course a majority is all that is necessary to adopt it. I think it is the type of amendment that it is unfortunate to have go into a bill of this type, because it emphasizes,

for purposes which I do not quite understand, certain disease. I think there are a lot of other diseases about which some language could have been used relating to various types of diseases, but I do not think it would have been necessarily helpful.

Mr. HARRIS. Mr. Speaker, will the gentleman yield?

Mr. O'HARA of Minnesota. I yield to the gentleman from Arkansas.

Mr. HARRIS. I appreciate the attitude of the gentleman and certainly understand from our discussions in the committee regarding this important legislation his feeling about it. I am sure the gentleman will agree that we made an effort to work out this bill to get it as satisfactory as possible.

Mr. O'HARA of Minnesota. I understand the situation fully, and why the amendment was agreed to.

Mr. HARRIS. For that reason, this amendment was offered and was adopted.

May I say that the Food and Drug Administration had no objection to the amendment. I have a letter to the committee from the Food and Drug Administration stating that it approves this amendment to the bill.

Mr. O'HARA of Minnesota. Mr. Speaker, I yield 2 minutes to the gentleman from California [Mr. McDONOUGH].

Mr. McDONOUGH. Mr. Speaker, I was a member of the Delaney committee which held numerous hearings on this subject in various parts of the United States. Although this legislation is necessary in order to protect the public, in my opinion, it is not as positive nor as strong as it should be on the basis of our hearings and the information that we obtained from witnesses. It is necessary largely because of the increase in the number of vendors and the competition between the various vendors of foods with added chemical additives to make the foods look better but which sometimes reduces the protein value and the nutritive value of the food. It is unfortunate that we have to have such legislation as this, but we have found it is necessary. Great volumes of food are turned out. All kinds of food is produced in ways to make it more attractive and to make it easier to bake cakes and to make it easier to bake pies and to make it easier to keep bread from molding on the shelves and so on, but with very little thought in many instances given to the effect these chemicals have on the nutritive value of the food. I favor this legislation as one means of protecting the public because I think that many of these chemicals are very dangerous in many instances and may be harmful to the health of many people throughout the Nation. These additives should be pretested before they are used. I trust, however, that the Committee on Interstate and Foreign Commerce will give further study and consideration to chemical additives to food and propose additional legislation to control the use of dangerous and deleterious chemicals which could and may be the source of infectious and contagious disease. The public health must be protected. Some of the cases that the Delaney committee heard testimony about from compe-

tent witnesses created doubt as to whether the use of these chemical additives in food did or did not create favorable conditions for the development of cancerous growth and other noxious diseases.

The following parts of the committee report on H. R. 13254 will give its purpose, history, and powerful provisions:

PURPOSES OF LEGISLATION

The purpose of the legislation is twofold:

1. To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and

2. To advance food technology by permitting the use of food additives at safe levels.

Existing law bars the use, even at safe levels, of additives which are poisonous or deleterious unless their use is required in production or cannot be avoided by good manufacturing practice. The Federal Government in order to prevent the use of an additive must prove that it is a poisonous or deleterious substance. The law thus gives rise to a dual problem. On the one hand, to prove an untested substance poisonous or deleterious may require approximately 2 years or more of laboratory experiments with small animals and during this period the Government cannot prevent the use of such a substance in food. On the other hand, present law entirely prohibits the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.

The Food and Drug Administration has pointed out the dangers to the public health resulting from the failure of the present law to require pretesting of food additives. On the other hand that agency agrees that the present law should be changed to permit the use of additives at safe levels in order to advance our food technology.

While the responsible elements of the affected industries traditionally have voluntarily undertaken to pretest food additives they are willing to assume this responsibility under a statutory mandate. Thus, those elements of the industry which in the past have used harmful additives or additives of unknown toxicity without pretesting will in the future under this legislation be required to assume the same duties as the responsible elements have heretofore voluntarily assumed.

Although there has been complete agreement as to the need for this legislation, there have been differences between the Food and Drug Administration and the affected industries with respect to procedures to be followed in determining the safety of an additive and the method of judicial review of such a determination. With respect to these controversial procedural questions, the committee feels the proposed legislation steers a course which satisfies both the need for protecting the public health and the legitimate interests of industry and Government in fair procedures.

HISTORY OF LEGISLATION

During the 81st Congress, a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics (better known as the Delaney committee, named after its chairman, Congressman JAMES J. DELANEY) was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in this respect. After extended hearings, the committee on June 30, 1952, filed a report (H. Rept. No. 2356, 82d Cong., 2d sess.) urging amending the present law so that chemicals employed in or on foods would be subjected

to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of the report were introduced by Congressman DELANEY and referred to this committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, the committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

During the 85th Congress, the Subcommittee on Health and Science held 11 days of hearings on 9 bills. The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee the scientific background with regard to the testing and evaluating of the safety of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of the hearings and after consideration of the various bills, the chairman of the subcommittee, Congressman JOHN BELL WILLIAMS of Mississippi, introduced a clean bill (H. R. 13254) which was reported unanimously by the subcommittee to the full committee.

The full committee unanimously reported the bill with one amendment which strikes out all after the enacting clause and inserts in place of the introduced bill a substitute. The principal difference between the proposed committee amendment and the introduced bill is the elimination of the provisions in the introduced bill relating to scientific advisory committees. The remaining differences are the result of clerical, technical, and clarifying changes.

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (including a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as intentional additives.

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as incidental additives.

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food-processing plants, are not covered by the legislation. These additives are generally referred to as accidental additives, since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term food additive as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Regulation to establish safety

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of a petition filed by any person (ordinarily the manufacturer of the additive) or on the Secretary's own initiative.

The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practical methods to determine the quantity of such additive left in or on food because of its use.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

Concept of safety

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any

possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the safety of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

I urge a favorable vote on this bill.

Mrs. SULLIVAN. Mr. Speaker, after all of the effort which a number of us in the House have put into the legislative drive to enact a law to control the use of unproved and doubtful chemical additives in food, I have no intention of attacking or denouncing this bill. It represents our only chance of getting a law through in this term of Congress. It is far better than the present law on the subject. Therefore, I will support it.

But at the same time I cannot pretend that I think the bill is adequate. It can be the means to keep manufacturers of processed foods from introducing new chemicals without adequate pretesting to assure their safety. It can enable the Food and Drug Administration to require manufacturers to do a thorough job of pretesting of proposed new additives.

EXTENDED GRACE PERIOD FOR ADDITIVES NOW IN USE

But for those additives now in use, including scores and perhaps as many as 150 of them which are not definitely

known to be safe, this bill leans over backward to allow every possible consideration for the manufacturers and users of those chemicals. For the next year and a half, at least, it will continue to be the responsibility of the Food and Drug Administration to prove any of these presently-in-use additives to be unsafe in order to have them eliminated from processed foods. This grace period in behalf of chemicals now in use could be extended as long as 2½ years from now.

After that period ends, whether it is 18 months or 30 months, depending upon the decision of the Secretary of Health, Education, and Welfare, the Food and Drug Administration can then, as I understand the bill, require that manufacturers produce proof of the safety of additives now in use, except, of course, for any substances which over the years have been clearly demonstrated by long use to be completely safe.

FURTHER DELAYS SHOULD NOT BE PERMITTED IN FUTURE

I can understand the technical difficulties of forcing all manufacturers of food items to begin the day after tomorrow, or even next January, to come in immediately with convincing scientific proof of the safety of all of the chemical additives they are now using. At the same time, experience has shown us that an extended grace period in any legislation affecting a long overdue reform in existing practices almost always seems to lead to additional moratoriums and delays and there always seems to be a good reason for allowing the industry affected more and more time in which to comply with the law.

I sincerely hope that does not happen in this instance. I shall certainly do everything I can to prevent it from happening. I urge that the food industry start at once to test and retest any doubtful additives now in use as a prelude to the kind of crackdown this proposed law eventually should accomplish.

NO "GRANDFATHER" CLAUSE INTENDED

Much of the food industry is on record in behalf of legislation of this general nature, and so here will be a good opportunity for the firms involved to prove their good faith, and to show that Congress has not made a grievous mistake by allowing this extended transition period for compliance in connection with additives now in use.

Otherwise, we can only believe that the support for additives control legislation from some segments of the food industry was based on an attempt to cover in and protect all existing additives through the legal device of a "grandfather's" clause. I am assured this bill as written does not provide such a grandfather's clause and it is on the basis of that assurance that I am going along with this bill—particularly as it now includes the amendment worked out with Congressman DELANEY to provide a definite prohibition against the use of any cancer-inducing substance.

CONGRESSMAN DELANEY HAS LED FIGHT FOR STRONG LEGISLATION

While this bill does not bear his name, and while I have no intention of dispar-

aging the hard work and the conscientious work of other Members of the House who have had important roles in the shaping of this legislation, I think it only fair to say that to the extent that this bill will really solve the problems of controlling food additives, the credit largely must go to the gentleman from New York [Mr. DELANEY]. It was his select committee some years ago which brought to the attention of the House and of the country, as a whole, the desperate need for legislation in this field. He has worked untiringly for such legislation for 8 years.

I have been proud to cosponsor Mr. DELANEY's strong legislative proposals in this field.

IMPERATIVE NEED FOR ADEQUATE APPROPRIATIONS

Mr. Speaker, I would like to make one further comment on the bill before us. I mentioned the transition or grace period on additives now in use. In that connection, I would like to impress upon the Eisenhower administration, and particularly the Bureau of the Budget, the overriding need for adequate appropriations for the Food and Drug Administration. The administration has been starving out that important agency. We in the Congress have had to force money upon the President, you might say, in order to provide even a less-than-adequate budget for the Food and Drug Administration. The Eisenhower administration's record on Food and Drug appropriations has been shamefully bad. I have called that fact to the attention of the House many times.

Under this bill, new additives will have to be pretested. This may provide additional responsibilities and duties for the Food and Drug Administration and I sincerely hope the Budget Bureau makes sure they have adequate funds for that phase of the work.

RESEARCH ON EXISTING ADDITIVES MUST NOT BE SHELVED

But even more important is the need for funds to continue research and study on those additives now in use—those which can be used for the next 18 months or 30 months unless and until FDA can prove them harmful.

The point I want to make as vigorously as I can in that connection is this: There must be no let-up, no shrugging off of responsibility by the Food and Drug Administration in analyzing and studying additives now in use, just because this bill will eventually—in 18 months or 30 months—provide machinery under which the manufacturers must prove them safe.

If there is any doubt about any additive now in use, the FDA should go after it vigorously. Money must be provided for that purpose. The Budget Bureau should not take the position that we can wait 18 months or 30 months for industry to prove these particular additives are safe or lose the right to use them. Too many Americans can be poisoned in the meantime by additives which may be found to be harmful.

NEXT OBJECTIVE: SAFETY OF COSMETICS

Mr. Speaker, I am pleased that we are finally passing a bill on chemical additives in food after all of these years of effort. I wish it were a better bill. But it can accomplish a great deal of good

if it is enacted into law. I congratulate all of those Members who have had a part in shaping the bill, and I sincerely hope the Senate will have an opportunity to act on the legislation so that a bill can be sent to the White House.

I now serve notice, Mr. Speaker, that I intend to do everything I can beginning at the start of the next session of Congress to enact similar legislation dealing with the safety of materials and chemicals used in cosmetics. I hope it does not take as long on that as it has taken to get action on the food additives. The problem is much the same and the solution also is much the same—that is, legislation to require the manufacturers to prove the safety of the chemicals they use rather than to force the Government to prove the chemicals to be unsafe.

The SPEAKER. The question is: Will the House suspend the rules and pass the bill, as amended?

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

FARM LEGISLATION

Mr. COOLEY asked and was given permission to address the House for 1 minute.)

Mr. COOLEY. Mr. Speaker, I would just like to announce that if I am recognized tomorrow by the Speaker I shall call up the bill, S. 4071, the Senate farm bill, and will move to suspend the rules and pass the bill with an amendment; and I ask at this time, Mr. Speaker, that I may have the privilege of printing it in the Record so that Members may know just what the amendment contains.

The SPEAKER. Is there objection to the request of the gentleman from North Carolina?

There was no objection.

The matter referred to is as follows:

Be it enacted, etc., That this act may be cited as the "Agricultural Act of 1958."

TITLE I—COTTON

Program for 1959 and 1960

SEC. 101. The Agricultural Act of 1949, as amended, is amended by adding the following new section:

"SEC. 102. Notwithstanding any other provisions of law—

"(a) for each of the 1959 and 1960 crops of upland cotton the Secretary of Agriculture is authorized and directed to offer the operator of each farm for which an allotment is established under section 344 of the Agricultural Adjustment Act of 1938, as amended, a choice of (A) the farm acreage allotment determined pursuant to, section 344 of the Agricultural Adjustment Act of 1938, as amended, and price support determined pursuant to section 101 of this act (the amount of cotton estimated to be produced on the additional acres allotted to producers selecting choice (B) for such year being taken into account in computing such support), except that for the 1959 crop the level of support shall be not less than 80 percent of parity, or (B) the farm acreage allotment determined pursuant to section 344 of the Agricultural Adjustment Act of 1938, as amended, increased by not to exceed 40 percent (such increased acreage allotment to be the acreage allotment for the farm for all purposes) and price support at a

level which is 15 percent of parity below the level of support established for producers who elect choice (A). Any person operating more than one farm, in order to be eligible for choice (B), must elect choice (B) for all farms for which he is operator. Not later than January 31 the Secretary shall determine and announce on the basis of his estimate of the supply percentage and the parity price as of the following August 1, the price support level for producers who elect choice (A) and choice (B), respectively and such price support levels shall be final. As soon as practicable after such announcement, the Secretary shall cause the operator (as shown on the records of the county committee) of each farm for which an allotment is established under section 344 of the Agricultural Adjustment Act of 1938, as amended, to be notified of the alternative levels of price support and the alternative acreage allotments available for his farm. The operator of each farm shall, within the time prescribed by the Secretary, notify the county committee in writing whether he desires the increased acreage allotment and the level of price support prescribed in choice (B) to be effective for the farm. If the operator fails to so notify the county committee within the time prescribed, he shall be deemed to have chosen the acreage allotment and the price support level prescribed in choice (A). The choice elected by the operator shall apply to all the producers on the farm. Notwithstanding the foregoing provisions of this subsection, the Secretary may permit the operator of a farm for which choice (B) is in effect to change to choice (A) where conditions beyond the control of the farm operator, such as excessive rain, flood, or drought, prevented the planting of acreage to cotton or having cotton acreage available for harvest on the farm in accordance with the plans of such operator in selecting choice (B). The additional acreage required to be allotted to farms under this section shall be in addition to the county, State, and national acreage allotments and the production from such acreage shall be in addition to the national marketing quota. The additional acreage authorized by this section shall not be taken into account in establishing future State, county, and farm acreage allotments. Notwithstanding any other provision of law, no farm participating in any cotton acreage reserve program established for 1959 under the Soil Bank Act shall receive an increased acreage allotment under the provisions of this section for 1959. Notwithstanding the provisions of section 344 (m) (2) any farm cotton acreage allotment increased as the result of the selection of choice (B) may not be released and reapportioned to any other farm. Price support shall be made available under this paragraph only to co-operators and only if producers have not disapproved marketing quotas for the crop.

"(b) for each of the 1959 and 1960 crops of upland cotton, price support shall be made available to producers who elect choice (A) through a purchase program. Price support shall be made available to producers who elect choice (B) through loans, purchases, or other operations.

"(c) the Commodity Credit Corporation is directed, during the period beginning August 1, 1959, and ending July 31, 1961, to offer any upland cotton owned by it for sale for unrestricted use at not less than 10 percent above the current level of price support prescribed in choice (B)."

Price support for 1961 and subsequent years

SEC. 102. (a) The Agricultural Act of 1949, as amended, is amended by adding a new section 103 as follows:

"Sec. 103. Notwithstanding the provisions of section 101 of this act, price support to co-operators for each crop of upland cotton, beginning with the 1961 crop, for which producers have not disapproved marketing

85TH CONGRESS
2D SESSION

H. R. 13254

IN THE SENATE OF THE UNITED STATES

AUGUST 14, 1958

Read twice and referred to the Committee on Labor and Public Welfare

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Food Additives Amend-
4 ment of 1958".

5 SEC. 2. Section 201, as amended, of the Federal Food,
6 Drug, and Cosmetic Act is further amended by adding at
7 the end of such section the following new paragraphs:

8 "(s) The term 'food additive' means any substance the
9 intended use of which results or may reasonably be expected

1 to result, directly or indirectly, in its becoming a component
2 or otherwise affecting the characteristics of any food (includ-
3 ing any substance intended for use in producing, manufac-
4 turing, packing, processing, preparing, treating, packaging,
5 transporting, or holding food; and including any source of
6 radiation intended for any such use), if such substance is not
7 generally recognized, among experts qualified by scientific
8 training and experience to evaluate its safety, as having been
9 adequately shown through scientific procedures (or, in the
10 case of a substance used in food prior to January 1, 1958,
11 through either scientific procedures or experience based on
12 common use in food) to be safe under the conditions of its
13 intended use; except that such term does not include—

14 “(1) a pesticide chemical in or on a raw agricultural
15 commodity; or

16 “(2) a pesticide chemical to the extent that it is
17 intended for use or is used in the production, storage, or
18 transportation of any raw agricultural commodity; or

19 “(3) any substance used in accordance with a sanc-
20 tion or approval granted prior to the enactment of this
21 paragraph pursuant to this Act or the Meat Inspection
22 Act of March 4, 1907 (34 Stat. 1260), as amended and
23 extended (21 U. S. C. 71 and the following).

24 “(t) The term ‘safe’, as used in paragraph (s) of this

1 section and in section 409, has reference to the health of man
2 or animal.”

3 SEC. 3. (a) Clause (2) of section 402 (a), as amended,
4 of such Act is amended to read as follows: “(2) (A) if it
5 bears or contains any added poisonous or added deleterious
6 substance (except a pesticide chemical in or on a raw agri-
7 cultural commodity and except a food additive) which is un-
8 safe within the meaning of section 406, or (B) if it is a
9 raw agricultural commodity and it bears or contains a pesti-
10 cide chemical which is unsafe within the meaning of section
11 408 (a), or (C) if it is, or it bears or contains, any food
12 additive which is unsafe within the meaning of section 409:
13 *Provided*, That where a pesticide chemical has been used in
14 or on a raw agricultural commodity in conformity with an
15 exemption granted or a tolerance prescribed under section
16 408 and such raw agricultural commodity has been subjected
17 to processing such as canning, cooking, freezing, dehydrat-
18 ing, or milling, the residue of such pesticide chemical remain-
19 ing in or on such processed food shall, notwithstanding the
20 provisions of sections 406 and 409, not be deemed unsafe if
21 such residue in or on the raw agricultural commodity has been
22 removed to the extent possible in good manufacturing prac-
23 tice and the concentration of such residue in the processed

1 food when ready to eat is not greater than the tolerance
2 prescribed for the raw agricultural commodity;”.

3 (b) Section 402 (a), as amended, of such Act is further
4 amended by striking out the period at the end thereof and
5 inserting in lieu thereof a semicolon and the following: “or
6 (7) if it has been intentionally subjected to radiation, unless
7 the use of the radiation was in conformity with a regulation
8 or exemption in effect pursuant to section 409.”

9 (c) The first sentence of section 406 (a) of such
10 Act is amended by striking out “clause (2)” wherever it
11 appears in such sentence and inserting in lieu thereof “clause
12 (2) (A)”.

13 SEC. 4. Chapter IV of such Act is amended by adding
14 at the end thereof the following new section:

15 “FOOD ADDITIVES

16 “Unsafe Food Additives

17 “SEC. 409. (a) A food additive shall, with respect to
18 any particular use or intended use of such additives, be
19 deemed to be unsafe for the purposes of the application
20 of clause (2) (C) of section 402 (a), unless—

21 “(1) it and its use or intended use conform to the
22 terms of an exemption which is in effect pursuant to sub-
23 section (i) of this section; or

24 “(2) there is in effect, and it and its use or
25 intended use are in conformity with, a regulation issued

under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

“Petition To Establish Safety

“(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

“(2) Such petition shall, in addition to any explanatory or supporting data, contain—

“(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

“(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

“(C) all relevant data bearing on the physical or other technical effect such additive is intended to pro-

1 duce, and the quantity of such additive required to
2 produce such effect;

3 “(D) a description of practicable methods for deter-
4 mining the quantity of such additive in or on food, and
5 any substance formed in or on food, because of its use;
6 and

7 “(E) full reports of investigations made with re-
8 spect to the safety for use of such additive, including full
9 information as to the methods and controls used in con-
10 ducting such investigations.

11 “(3) Upon request of the Secretary, the petitioner shall
12 furnish (or, if the petitioner is not the manufacturer of such
13 additive, the petitioner shall have the manufacturer of such
14 additive furnish, without disclosure to the petitioner) a full
15 description of the methods used in, and the facilities and
16 controls used for, the production of such additive.

17 “(4) Upon request of the Secretary, the petitioner shall
18 furnish samples of the food additive involved, or articles used
19 as components thereof, and of the food in or on which the
20 additive is proposed to be used.

21 “(5) Notice of the regulation proposed by the petitioner
22 shall be published in general terms by the Secretary within
23 thirty days after filing.

1 “Action on the Petition

2 “(c) (1) The Secretary shall—

3 “(A) by order establish a regulation (whether or
4 not in accord with that proposed by the petitioner)
5 prescribing, with respect to one or more proposed uses
6 of the food additive involved, the conditions under which
7 such additive may be safely used (including, but not lim-
8 ited to, specifications as to the particular food or classes
9 of food in or in which such additive may be used, the
10 maximum quantity which may be used or permitted to
11 remain in or on such food, the manner in which such
12 additive may be added to or used in or on such food, and
13 any directions or other labeling or packaging require-
14 ments for such additive deemed necessary by him to as-
15 sure the safety of such use), and shall notify the peti-
16 tioner of such order and the reasons for such action; or

17 “(B) by order deny the petition, and shall notify
18 the petitioner of such order and of the reasons for such
19 action.

20 “(2) The order required by paragraph (1) (A) or
21 (B) of this subsection shall be issued within ninety days
22 after the date of filing of the petition, except that the Secre-

1 tary may (prior to such ninetieth day), by written notice
2 to the petitioner, extend such ninety-day period to such
3 time (not more than one hundred and eighty days after the
4 date of filing of the petition) as the Secretary deems neces-
5 sary to enable him to study and investigate the petition.

6 “(3) No such regulation shall issue if a fair evaluation
7 of the data before the Secretary—

8 “(A) fails to establish that the proposed use of the
9 food additive, under the conditions of use to be speci-
10 fied in the regulation, will be safe: *Provided*, That no
11 additive shall be deemed to be safe if it is found to in-
12 duce cancer when ingested by man or animal, or if it
13 is found, after tests which are appropriate for the evalua-
14 tion of the safety of food additives, to induce cancer
15 in man or animal; or

16 “(B) shows that the proposed use of the additive
17 would promote deception of the consumer in violation
18 of this Act or would otherwise result in adulteration
19 or in misbranding of food within the meaning of this Act.

20 “(4) If, in the judgment of the Secretary, based upon
21 a fair evaluation of the data before him, a tolerance limita-
22 tion is required in order to assure that the proposed use
23 of an additive will be safe, the Secretary—

24 “(A) shall not fix such tolerance limitation at a
25 level higher than he finds to be reasonably required to

1 accomplish the physical or other technical effect for
2 which such additive is intended; and

3 “(B) shall not establish a regulation for such pro-
4 posed use if he finds upon a fair evaluation of the data
5 before him that such data do not establish that such use
6 would accomplish the intended physical or other techni-
7 cal effect.

8 “(5) In determining, for the purposes of this section,
9 whether a proposed use of a food additive is safe, the Sec-
10 retary shall consider among other relevant factors—

11 “(A) the probable consumption of the additive
12 and of any substance formed in or on food because of
13 the use of the additive;

14 “(B) the cumulative effect of such additive in the
15 diet of man or animals, taking into account any chemi-
16 cally or pharmacologically related substance or sub-
17 stances in such diet; and

18 “(C) safety factors which in the opinion of experts
19 qualified by scientific training and experience to evaluate
20 the safety of food additives are generally recognized as
21 appropriate for the use of animal experimentation data.

22 “Regulation Issued on Secretary’s Initiative

23 “(d) The Secretary may at any time, upon his own
24 initiative, propose the issuance of a regulation prescribing,

1 with respect to any particular use of a food additive, the
2 conditions under which such additive may be safely used,
3 and the reasons therefor. After the thirtieth day following
4 publication of such a proposal, the Secretary may by order
5 establish a regulation based upon the proposal.

6 “Publication and Effective Date of Orders

7 “(e) Any order, including any regulation established
8 by such order, issued under subsection (c) or (d) of this
9 section, shall be published and shall be effective upon publi-
10 cation, but the Secretary may stay such effectiveness if, after
11 issuance of such order, a hearing is sought with respect to
12 such order pursuant to subsection (f).

13 “Objections and Public Hearing

14 “(f) (1) Within thirty days after publication of an
15 order made pursuant to subsection (c) or (d) of this
16 section, any person adversely affected by such an order may
17 file objections thereto with the Secretary, specifying with
18 particularity the provisions of the order deemed objection-
19 able, stating reasonable grounds therefor, and requesting a
20 public hearing upon such objections. The Secretary shall,
21 after due notice, as promptly as possible hold such public
22 hearing for the purpose of receiving evidence relevant and
23 material to the issues raised by such objections. As soon as
24 practicable after completion of the hearing, the Secretary

1 shall by order act upon such objections and make such order
2 public.

3 “(2) Such order shall be based upon a fair evaluation
4 of the entire record at such hearing, and shall include a
5 statement setting forth in detail the findings and conclusions
6 upon which the order is based.

7 “(3) The Secretary shall specify in the order the date
8 on which it shall take effect, except that it shall not be
9 made to take effect prior to the ninetieth day after its
10 publication, unless the Secretary finds that emergency con-
11 ditions exist necessitating an earlier effective date, in which
12 event the Secretary shall specify in the order his findings as
13 to such conditions.

14 “Judicial Review

15 “(g) (1) In a case of actual controversy as to the
16 validity of any order issued under subsection (f), including
17 any order thereunder with respect to amendment or repeal
18 of a regulation issued under this section, any person who will
19 be adversely affected by such order may obtain judicial
20 review by filing in the United States Court of Appeals for
21 the circuit wherein such person resides or has his principal
22 place of business, or in the United States Court of Appeals
23 for the District of Columbia Circuit, within sixty days after

1 the entry of such order, a petition praying that the order
2 be set aside in whole or in part.

3 “(2) A copy of such petition shall be forthwith served
4 upon the Secretary, or upon any officer designated by him
5 for that purpose, and thereupon the Secretary shall certify
6 and file in the court a transcript of the proceedings and the
7 record on which he based his order. Upon such filing, the
8 court shall have exclusive jurisdiction to affirm or set aside
9 the order complained of in whole or in part. The findings
10 of the Secretary with respect to questions of fact shall be
11 sustained if based upon a fair evaluation of the entire record
12 at such hearing. The court shall advance on the docket and
13 expedite the disposition of all causes filed therein pursuant
14 to this section.

15 “(3) The court, on such judicial review, shall not sustain
16 the order of the Secretary if he failed to comply with any
17 requirement imposed on him by subsection (f) (2) of this
18 section.

19 “(4) If application is made to the court for leave to
20 adduce additional evidence, the court may order such addi-
21 tional evidence to be taken before the Secretary and to be
22 adduced upon the hearing in such manner and upon such
23 terms and conditions as to the court may seem proper, if
24 such evidence is material and there were reasonable grounds
25 for failure to adduce such evidence in the proceedings below.

1 The Secretary may modify his findings as to the facts and
2 order by reason of the additional evidence so taken, and
3 shall file with the court such modified findings and order.

4 “(5) The judgment of the court affirming or setting
5 aside, in whole or in part, any order under this section shall
6 be final, subject to review by the Supreme Court of the
7 United States upon certiorari or certification as provided
8 in section 1254 of title 28 of the United States Code. The
9 commencement of proceedings under this section shall not,
10 unless specifically ordered by the court to the contrary,
11 operate as a stay of an order.

12 “Amendment or Repeal of Regulations

13 “(h) The Secretary shall by regulation prescribe the
14 procedure by which regulations under the foregoing pro-
15 visions of this section may be amended or repealed, and
16 such procedure shall conform to the procedure provided
17 in this section for the promulgation of such regulations.

18 “Exemptions for Investigational Use

19 “(i) Without regard to subsections (b) to (h), inclu-
20 sive, of this section, the Secretary shall by regulation provide
21 for exempting from the requirements of this section any
22 food additive, and any food bearing or containing such addi-
23 tive, intended solely for investigational use by qualified ex-
24 perts when in his opinion such exemption is consistent with
25 the public health.”

1 SEC. 5. Section 301 (j) of such Act is amended by
2 inserting "409," after "404,".

3 SEC. 6. (a) Except as provided in subsections (b) and
4 (c) of this section, this Act shall take effect on the date of
5 its enactment.

6 (b) Except as provided in subsection (c) of this sec-
7 tion, section 3 of this Act shall take effect on the one hun-
8 dred and eightieth day after the date of enactment of this
9 Act.

10 (c) With respect to any particular commercial use of a
11 food additive, if such use was made of such additive before
12 January 1, 1958, section 3 of this Act shall take effect—

13 (1) either (A) one year after the effective date
14 established in subsection (b) of this section, or (B) at
15 the end of such additional period (but not later than
16 two years from such effective date established in sub-
17 section (b)) as the Secretary of Health, Education, and
18 Welfare may prescribe on the basis of a finding that
19 such extension involves no undue risk to the public
20 health and that conditions exist which necessitate the
21 prescribing of such an additional period, or

22 (2) on the date on which an order with respect to
23 such use under section 409 of the Federal Food, Drug,
24 and Cosmetic Act becomes effective,
25 whichever date first occurs.

1 SEC. 7. Nothing in this Act shall be construed to exempt
2 any meat or meat food product or any person from any
3 requirement imposed by or pursuant to the Meat Inspection
4 Act of March 4, 1907, 34 Stat. 1260, as amended and
5 extended (21 U. S. C. 71 and the following) .

Passed the House of Representatives August 13, 1958.

Attest:

RALPH R. ROBERTS,

Clerk.

85TH CONGRESS
2d Session

H. R. 13254

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

AUGUST 14, 1958

Read twice and referred to the Committee on Labor
and Public Welfare

General Description. - The

... ..

... ..

... ..

... ..

... ..

... ..

... ..

... ..

SENATE - August 15

1. SUPPLEMENTAL APPROPRIATION BILL, 1959. Passed with amendments this bill, H. R. 13450. pp. 16305-11, 16431-54, 16457-73 (See Digest 140 for USDA items.)
Agreed to an amendment by Sen. Neuberger (for himself and others) to add an item of \$100,000, to remain available until expended, for the Outdoor Recreation Review Commission. pp. 16442-3
Sen. Cooper inserted his statement favoring the emergency conservation measures program. pp. 16469-60
Sen. Mundt inserted the committee's statement on reduction of personnel, and he and Sen. Dworshak commended the statement. pp. 16470-3
2. FARM PROGRAM. Sens. Ellender, Johnston, Eastland, Humphrey, Aiken, Young, and Thyne were appointed conferees on S. 4071, the farm bill. The text of the bill, as passed by the House, was printed in the Record. pp. 16314-17
3. DAIRY EXPORTS. The Agriculture and Forestry Committee voted to disapprove S. 4013, to provide for an export program for dairy products. p. D857
4. WATERSHED PROJECTS. The Agriculture and Forestry Committee approved the following watershed projects: Busseron Creek, Ind.; Crooked Creek, Iowa; and Furnace Brook-Middle River, Conn. and Mass. p. D857
5. FOOD ADDITIVES. The Labor and Public Welfare Committee ordered reported with amendments H. R. 13254, to regulate food additives. p. D857
6. DEBT LIMIT. The Finance Committee reported with amendments H. R. 13580, to increase the debt limit. As reported, the bill would (1) set the permanent limit at \$283 billion and (2) set the temporary limit at \$288 billion until June 30, 1959, at which time it would revert to the permanent limit. (S. Rept. 2389) p. 16263
Sen. Symington recommended that the Treasury announce its long-term borrowing programs and that public needs have a higher priority than economy in expenditures. p. 16281
7. FORESTRY; LAND UTILIZATION. The Agriculture and Forestry Committee reported without amendment H. R. 8481, to extend title IV of the Agricultural Act of 1956, relating to forestry, to Hawaii (S. Rept. 2415), and H. R. 12494, to authorize this Department, in selling or agreeing to the sale of lands to N. C., to permit the State to sell or exchange such lands for private purposes (S. Rept. 2416). pp. 16263-4
8. RIVER BASINS. Passed without amendment S. 4266, to establish the U. S. Study Commission on the Neches, Trinity, Brazos, Colorado, Guadalupe-San Antonio, Nueces, and San Jacinto River Basins and intervening areas. pp. 16284-6, 16262
Passed as reported S. 4192, to authorize modification of the comprehensive plan of improvement for the Trinity River basin, Tex. pp. 16286-7
9. RECLAMATION. Passed as reported S. 3648, to authorize construction and operation of the Navaho Indian irrigation project. pp. 16287-91
Passed as reported S. 1887, to authorize construction of the San Luis Unit of the Central Valley project, Calif. pp. 16291-303
10. TAXES. Agreed to the conference reports on H. R. 7125 and H. R. 8381, to make technical changes in the tax laws. The House agreed to the report on H. R. 8381. These bills will now be sent to the President. pp. 16322, 16311-3
11. SOCIAL SECURITY. Began debate on H. R. 13549, to increase the benefits under the Social Security Act. pp. 16473-83

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF BUDGET AND FINANCE
(For Department Staff Only)

Issued August 18, 1958
For actions of Aug. 15 and 16, 1958
85th-2d, Nos. 141
and 142

CONTENTS

Adjournment.....	31,41	Forestry..	7,16,34,40,44,61	Pesticides.....	45
Appropriation.....	1,40,56	Housing.....	28,30	Prices.....	58
Area redevelopment.....	12	Imports.....	62	Property.....	29
Budgeting.....	48	Information.....	59	Public Law 480.....	40
Butter.....	20	Land entries.....	65	Purchasing.....	27
Cheese.....	20	Land utilization.....	7	Reclamation.....	9,25
Crop insurance.....	15	Leases.....	29	Research.....	17,30,42
Dairy exports.....	3	Legislative program..	30,40	River basins.....	8
Debt limit.....	6,40,51	Livestock.....	40,47	Saline water.....	55
Disaster loans.....	14	Lobbying.....	39	School lunch.....	30
Education.....	24,30	Meatpacking.....	43	Small business.....	27,53
Electrification...37,46,49		Military construction..	18	Social security.....	11,35
Emergency Conservation...1		Minerals.....	23,30	Surplus commodities....	33
Employment.....	52	Nominations.....	38	Surplus property.....	57
Farm program....2,22,32,42		Oleomargarine.....	40	Taxes.....	10,19
Food additives.....	5	Onion futures.....	13	Textiles.....	36
Food stamp.....	30	Palm oil.....	19	Water resources...21,54,66	
Foreign trade.....	33,50,64	Personnel.....	1,26,60,63	Watershed projects....	4,40

HIGHLIGHTS: Senate passed supplemental appropriation bill. Senate conferees were appointed on farm bill. House passed area redevelopment bill. House agreed to conference report on bill prohibiting onion futures trading. House committee reported bill to require State contributions to disaster relief. Senate committee rejected dairy export bill. Senate committee reported debt-limit increase bill.

22. **WATER RESOURCES.** Passed with amendments H. R. 5497, to authorize Federal assistance for certain fish and wildlife development projects under the Watershed Protection and Flood Prevention Act. Agreed to two amendments by Sen. Cotton to exclude recreational facilities from the bill. pp. 16716-19
- Passed with amendment H. R. 12216, to designate a dam on the Cumberland River near Carthage, Tenn., as the Cordell Hull Dam, and to establish a U. S. study commission on certain Texas river basins. pp. 16634-5
- Passed without amendment H. J. Res. 585, to authorize the Secretary of the Interior to conduct studies into the feasibility of furnishing water from the Central Valley Project to the counties of Santa Clara, San Benito, Santa Cruz, and Monterey, Calif., by way of the Pacheco Tunnel route or other means. This measure will now be sent to the President. p. 16638
- Sen. Neuberger discussed S. 3185, to require the FPC to secure approval by the Secretary of the Interior of any license affecting fish and wildlife resources. He asserted that the amendment proposed by Sen. Morse, to require only that the FPC receive recommendations but not be bound by them, would maintain the present situation in FPC, which, he alleged, "has neither special competence nor special sympathy for conservation goals and methods, when they would militate against construction of a power project." pp. 16622-26
- Sen. Watkins inserted two articles on Russian hydro-power development which asserted that their program was behind schedule, and greater emphasis was now being placed on thermal power generation. pp. 16617-18
- Sen. Johnson discussed the development of Texas' water resources and urged the development of a unified program. pp. 16611-12
23. **FORESTRY.** Passed without amendment H. R. 8481, to extend title IV of the Agricultural Act of 1956, relating to forestry, to Hawaii. This bill will now be sent to the President. p. 16638
- Sen. Humphrey inserted resolutions from the cities of Tower, Eveleth, and Kinney, Minn., urging the appropriation of additional funds for construction projects planned for the Superior National Forest. p. 16613
24. **LAND UTILIZATION.** Passed without amendment H. R. 12494, to authorize this Department, in selling or agreeing to the sale of certain lands to N. C., to permit the State to sell or exchange such lands for private purposes. This bill will now be sent to the President. p. 16638
25. **ELECTRIFICATION.** Passed without amendment S. 3571, to provide for equal treatment of all State-owned hydro-electric power projects with respect to the taking over of such projects by the U. S. p. 16633
- Sen. Humphrey inserted a resolution from the East River Electric Power Cooperative urging the enactment of S. 2990 and H. R. 11762, to transfer certain REA functions from the Secretary to the REA Administrator. pp. 16612-13
26. **RESEARCH.** Passed with amendment S. 3268, to provide various amendments to the National Science Foundation Act. pp. 16631-2
27. **ADMINISTRATIVE ORDERS.** The Judiciary Committee reported without amendment H. R. 6789, to provide for reasonable notice of applications to the U. S. courts of appeals for interlocutory relief against the orders of certain administrative agencies (S. Rept. 2435). p. 16613
28. **FOOD ADDITIVES.** The Labor and Public Welfare Committee reported with amendments H. R. 13254, to amend the Federal Food, Drug, and Cosmetic Act so as to prohibit the use in foods of additives which have not been adequately tested to establish their safety (S. Rept. 2422). p. 16613

Aug 18, 1958

11. PERSONNEL. Passed as reported H. R. 9407, to provide additional opportunity for certain employees to obtain career-conditional and career appointments in the competitive service. p. 16848
Passed without amendment S. 4004, to encourage transfers of Federal employees for service with international organizations. This bill will now be sent to the President. pp. 16849-49
Passed as reported S. 3195, to authorize certain retired Federal personnel to accept and wear decorations, presents, and other things tendered them by certain foreign countries. pp. 16850-66
12. INSPECTION SERVICES. Passed without amendment S. 3873, to permit the interchange of inspection services between executive agencies without reimbursement or transfer of funds. This bill will now be sent to the President. p. 16867
13. MINING CLAIMS. Passed over without prejudice, at the request of Rep. Saylor, S. 2039, to clarify the requirements with respect to the performance of labor imposed as a condition for the holding of mining claims on Federal lands pending the issuance of patents therefor. p. 16867
14. EDUCATION. The Rules Committee reported a resolution for consideration of H. 13247, the national defense education bill. p. 16887
15. SALINE WATER. The "Daily Digest" states that conferees agreed to file a report on "S. J. Res. 135, relating to the conversion of saline water to potable uses." p. D871
16. LEGISLATIVE PROCEDURE. Rep. Arends objected to scheduling numerous bills in the House for consideration under suspension of the rules, stating that "some of these bills you have scheduled are of major importance and highly controversial and extremely costly to the American people." p. 16804

SENATE

17. FARM PROGRAM. Concurred in the House amendment to S. 4071, the Senate farm bill. This bill will now be sent to the President. (pp. 16748-59) See Digest 140 regarding provisions of the House Amendment.
18. FARM LABOR. Passed without amendment H. R. 10360, to extend the Mexican farm labor program until June 30, 1961. This bill will now be sent to the President. p. 16659
19. LIVESTOCK DISEASES. Passed as reported H. R. 12126, to extend to wild animals the same prohibition against entry into the U. S. as domestic animals from any country where rinderpest or foot-or-mouth disease exists. p. 16661
20. MARGARINE. Passed with amendment H. R. 912, to amend the Navy ration statute to permit the serving of oleo or margarine. pp. 16661-2
21. TEXTILES. Passed with amendments H. R. 469, to protect producers and consumer against misbranding and false advertising of the fiber content of textile fiber products. (pp. 16720-1, 16725, 16726-45)
Adopted the committee amendments, and an amendment by Sen. Javits, to eliminate language requiring the labeling of the containers of imported textile products (p. 16744).

FOOD ADDITIVES AMENDMENT OF 1958

AUGUST 18 (legislative day, AUGUST 16), 1958.—Ordered to be printed

Mr. Hill, from the Committee on Labor and Public Welfare,
submitted the following

REPORT

[To accompany H. R. 13254]

The Committee on Labor and Public Welfare, to whom was referred the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, having considered the same, report favorably thereon, with amendments, and recommend that the bill do pass.

EXPLANATION

The two amendments which this committee has added to the bill as passed by the House, which are discussed in detail below, do not in any way change the substance or content of the bill which passed the House of Representatives without dissent. They deal, not with the content of that bill, but with related problems regarding the ability of the Department of Health, Education, and Welfare to secure and retain the services of individuals unquestionably qualified to protect and to better the health of our people.

In explanation of the bill sent us by the House, passage of which your committee recommends with additions but without change in any of its provisions, we would point out first that under existing law the Federal Government is unable to prevent the use in foods of a poisonous or deleterious substance until it first proves that the additive is poisonous or deleterious. To establish this proof through experimentation with generations of mice or other animals may require 2 years or even more on the part of the relatively few scientists the Food and Drug Administration is able to assign to a particular problem. Yet, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death.

Your committee is pleased to report to the Congress that an analysis of the hearings on this and related measures which have been held over a period of some 6 years shows clearly that an overwhelming percentage of our food processors—and by this we mean the processors of well over 95 percent of the foodstuffs Americans eat—have voluntarily undertaken, at considerable expense to themselves, to thoroughly test and prove safe to humans any additives they have considered adding to foods to make them more appetizing, better keeping, more palatable, or otherwise improved. Nonetheless, existing law permits any processor who chooses to pay no heed either to the public's health or to his continuance in one particular line of business to unfairly compete with responsible processors, to defy the Food and Drug Administration and to endanger the health of millions by using an untested additive for as long a time as it may take for the Government to suspect the deleteriousness of his additives, schedule research into its properties and effects, and, finally—perhaps years later—to begin the years-long experiments needed to prove the particular additive safe or unsafe. This huge loophole is 1 of 2 flaws in existing law which, through this measure, we are attempting to fill. This bill, if enacted, will require the processor who wants to add a new and unproven additive to accept the responsibility now voluntarily borne by all responsible food processors of first proving it to be safe for ingestion by human beings.

The second flaw in existing law which has proved detrimental to consumers, to processors, and to our national economy and which this bill seeks to remove is a provision which has inadvertently served to unnecessarily proscribe the use of additives that could enable the housewife to safely keep food longer, the processor to make it more tasteful and appetizing, and the Nation to make use of advances in technology calculated to increase and improve our food supplies. Your committee agrees with the Food and Drug Administration that existing law should be changed to permit the use of such additives as our technological scientists may produce and which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted by the Food and Drug Administration as safe. The rulings of the Department of Health, Education, and Welfare on such questions are, of course, subject to judicial review. The concept of safety used throughout this bill centers on the question of whether a substance is safe for use with reference to the health of man or animal. As the report of the Committee on Interstate and Foreign Commerce of the House of Representatives states, "Safety requires proof of reasonable certainty that no harm will result from the proposed use of an additive." Conscious of the fact that any substance or, for that matter, any particular food known to be good for the health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, the committee agrees with the Food and Drug Administration that, instead of insisting on proof beyond any possible doubt that no harm will result under any conceivable circumstances from the use of a particular additive—which could, of course, occur if an individual decided to eat a pound of salt or drink 4 gallons of pure water in an hour—the test which should determine whether or not a particular additive may be used in a specific percentage of relationship to the volume of the product to which it might be added should be that of

reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal, subject to the procedural safeguards provided in the bill which assure the right to hearing and judicial review.

The bill, the passage of which your committee recommends, would correct both of these flaws in existing law. It would put upon the processor rather than our Government the burden of proving that a newly discovered substance which a processor of foodstuffs proposes to add to the food we eat is safe. It would make possible the use of additives discovered by our scientists which, having been adjudged safe for humans and animals when used in or within certain quantitative limits, could materially advance our ability to make more wholesome foods available to more people at all seasons and, perhaps, we hope, to assure to ourselves and others the ability to stockpile supplies of healthful and appetizing foods over such long periods of time as emergencies might make either desirable or essential.

HISTORY OF LEGISLATION

This bill, the passage of which your committee recommends as urgent, is the product of some 6 years of the most extensive and intensive hearings on legislative proposals in a particular field of which we have knowledge. To us it represents the workings of a free society at its best. Through public hearings, carried on over a period of 6 years, not only in every one of those 6 years but in every part of the country as well, the Committee on Interstate and Foreign Commerce of the House of Representatives was able to effect a meeting of minds and to send us a bill which has the support not only of those required by law to protect the Nation's health—the officials of the Food and Drug Administration—but also of the overwhelming majority of all those engaged in processing and selling the foodstuffs essential to the Nation's health.

Passage of this bill is strongly recommended not only by the executive branch of our Government but by each of the organizations connected with the processing and distribution of foods listed below:

- National Canners Association
- National Dairy Products Corp., Kraft Foods division
- Grocery Manufacturers of America
- Millers National Federation
- American Bakers Association
- Manufacturing Chemists Association
- Dairy Industry Committee, speaking for—
 - The American Butter Institute
 - The American Dairy Milk Institute
 - The Evaporated Milk Association
 - The International Association of Ice Cream Manufacturers
 - The Milk Industry Foundation
 - The National Cheese Institute
 - The National Creameries Association

During the 81st Congress, a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics (better known as the Delaney committee, named after its chairman, Congressman James J. Delaney) was created in the House of Representatives to study the need to amend the present Federal Food, Drug, and Cosmetic Act in

this respect. After extended hearings, the committee on June 30, 1952, filed a report (H. Rept. No. 2356, 82d Cong., 2d sess.) urging amending the present law so that chemicals employed in or on foods would be subjected to substantially the same safety requirements as exist in the law for new drugs.

Bills to accomplish the objectives of that report were introduced by Congressman Delaney and referred to that committee during the 83d Congress and subsequent Congresses, and other Members of Congress introduced numerous bills differing from the prototype bills primarily with respect to agency procedure and judicial review.

During the 83d Congress, that committee held hearings and reported favorably related legislation providing for the pretesting of, and the establishment of safe tolerances for, pesticide chemicals. This bill was enacted into law (Public Law 518, 83d Cong.).

During the 2d session of the 84th Congress, the Subcommittee on Health and Science of the Committee on Interstate and Foreign Commerce of the House of Representatives, under the chairmanship of the late full committee chairman, J. Percy Priest, held 5 days of hearings on 10 bills dealing with chemical additives in and on food. The hearings indicated basic agreement with regard to the need for chemical additive legislation, but also considerable disagreement with regard to the agency and judicial review procedures to be followed in determining the safety of chemical additives. This disagreement was not resolved, and no chemical additive legislation was enacted during the 84th Congress.

During the 85th Congress, that subcommittee held 11 days of hearings on 9 related bills. The hearings included 2 days of testimony by a panel of outstanding scientists and experts selected by the National Academy of Sciences at the request of the subcommittee, to give the subcommittee scientific background with regard to the testing and evaluating of chemical additives. The subcommittee also heard witnesses from industry, labor, and consumer organizations, representatives from the Department of Health, Education, and Welfare, including those from the Food and Drug Administration, and the chief judge of the third judicial circuit appearing on behalf of the Judicial Conference of the United States.

As a result of those hearings and after consideration of the many related bills on this subject before the subcommittee, its chairman, Congressman John Bell Williams of Mississippi, introduced a clean bill (H. R. 13254) which was reported unanimously by the subcommittee to the full Committee on Interstate and Foreign Commerce of the House of Representatives. That bill with 1 minor committee amendment which we shall discuss below passed the House without dissent and with the 2 amendments added by your committee is the bill now under consideration.

PRINCIPAL PROVISIONS OF LEGISLATION

Substances covered by legislation

Pretesting is required under this legislation only with respect to those food additives which are not generally recognized among competent experts as having been adequately shown to be safe under the conditions of their intended use. An additive may be shown to be safe either by means of scientific procedures (including

a review of the existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food.

The legislation covers substances which are added intentionally to food. These additives are generally referred to as "intentional additives."

The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as "incidental additives."

The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.

On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as "accidental additives," since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.

Sources of radiation (including radioactive isotopes, particle accelerators and X-ray machines) intended for use in processing food are included in the term "food additive" as defined in this legislation.

Exempted from the scope of the legislation are (1) pesticide chemicals in or on raw agricultural commodities which are already covered by the pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (Public Law 518, 83d Cong.); (2) residues of pesticide chemicals unavoidably remaining on processed foods not in excess of tolerances prescribed by Food and Drug Administration for raw agricultural commodities; and (3) substances already approved under the provisions of the Federal Food, Drug, and Cosmetic Act or the Meat Inspection Act of March 4, 1907.

The Secretary is given authority by this legislation to exempt by regulation food additives for investigational use by qualified experts when consistent with the public health.

Regulation to establish safety

A regulation prescribing the conditions under which an additive may be safely used may be issued by the Secretary of Health, Education, and Welfare either on the basis of a petition filed by any person (ordinarily the manufacturer of the additive) or on the Secretary's own initiative.

The petition would set forth the name and all pertinent information concerning the additive, including, where available, its chemical identity and composition; full reports of scientific investigations of safety for use; the conditions of the proposed use of such additive; all relevant data bearing on the physical or other technical effect such additive is intended to produce; the quantity required to produce such effect; when requested by the Secretary, the methods used to produce the additive; and a description of practicable methods to

determine the quantity of such additive left in or on food because of its use.

In addition, upon request of the Secretary, the petitioner would be required to furnish (or, if he is not the manufacturer of the additive, to have the manufacturer furnish) to the Secretary a full description of the methods, facilities, and controls used for the production of the additive. Samples of the additive or its components, or of the food in which it is to be used, would also have to be furnished if requested by the Secretary.

Trade secrets supplied to the Secretary would be protected under this legislation from unauthorized disclosure by departmental personnel.

The Secretary would either, by order, establish a regulation prescribing the conditions under which such additive may be safely used, or he would, by order, deny the petition and notify the petitioner of the reasons for such action. Such orders would be issued within 90 days after the date of filing of the petition unless the Secretary, by written notice to the petitioner, extends such period for not more than an additional 90 days to enable him to study the petition.

✓ Concept of safety

The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.

This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.

In determining the “safety” of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related substances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.

The legislation adopts this concept of safety by requiring the Secretary to consider in addition to information with regard to the specific additive in question, among others, the following relevant factors: (1) the probable consumption of the additive and of any substance formed in or on food because of the use of such additive; (2) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substances in such diet; and (3) safety factors which qualified experts consider appropriate for the use of animal experimentation data.

In determining the safety of an additive, the Secretary would have to consider not only the food to which the additive is directly added, but also other foods derived from such foods. For example, in evaluating the safety of an additive for poultry feed, the Secretary would

have to consider any residues that might appear in eggs produced by the poultry. Similarly, in determining the safety of additive-treated cattle feed, account would have to be taken of residues of the additive in the milk or edible flesh of the animal.

Since the scientific investigation and the other relevant data to be taken into consideration by the Secretary include information with respect to possible cancer causing characteristics of a proposed additive, the public will be protected from possible harm on this count.

Grounds for denial of petition

The Secretary would deny a petition to establish the safety of an additive if the data before the Secretary fail to establish that the proposed use of the additive under the specified conditions of use will be safe.

The Secretary could also deny a petition on the ground that the proposed use of the additive would promote deception of the consumer in violation of the Federal Food, Drug, and Cosmetic Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Food and Drug Act.

Tolerance limitations

In the case of an additive which, in the judgment of the Secretary based upon a fair evaluation of the data before him, requires a tolerance limitation in order to assure that the proposed use of such additive will be safe, the legislation establishes two standards:

(1) The Secretary may not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(2) The Secretary may not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

The phrase "physical or other technical effect" refers to the objective effect which the additive may have on the appearance, flavor, texture, or other aspects of a food. The question of whether an additive produces such effect (or how much of an additive is required for such effect) is a factual one, and does not involve any judgment on the part of the Secretary of whether such effect results in any added "value" to the consumer of such food or enhances the marketability from a merchandising point of view.

Public hearings

Any person adversely affected by an order of the Secretary may file objections thereto and request a public hearing. At such hearings the Secretary would receive evidence relevant and material to the issues raised and would by order act upon such objections.

Judicial review

The problem of the scope of judicial review under this legislation is an important one. It was discussed exhaustively by several witnesses before the House subcommittee, including a Federal judge who testified on behalf of the Judicial Conference of the United States.

Your committee agrees with the House that the Secretary's findings of fact and orders should not be based on isolated evidence in the record, which evidence in and of itself may be considered substantial

without taking account of contradictory evidence of possibly equal or even greater substance.

Following the appearance before it of a panel of outstanding scientists, the House subcommittee expressed itself as impressed with the wide range of scientific judgment factors which are involved in determining the safety of a food additive. Considering the eminent qualifications of all the scientists and experts who participated in these panel hearings, the scientific testimony of any one of the participants must be considered "substantial evidence." Nevertheless, any conclusions based solely on the scientific judgment of any one of the participants without taking account of contradictory scientific views expressed by other participants cannot be considered conclusions based upon a fair evaluation of the entire record.

Thus, under this legislation, the Secretary's findings of fact and orders based thereon must be based upon a fair evaluation of the entire record. The committee adopted the language "fair evaluation of the entire record" because it seemed to express most clearly the standard of judicial review of administrative findings of fact and orders based thereon which the committee feels should prevail.

The bill provides that the reviewing court shall not sustain the order of the Secretary if he failed to base such order upon a fair evaluation of the entire record at such hearing, or if he failed to include in such order a statement setting forth in detail the findings and conclusions upon which the order is based. The court must sustain the findings of the Secretary with respect to questions of fact if based upon a fair evaluation of the entire record.

Judicial review of any order of the Secretary under this legislation may be obtained in the United States court of appeals for the circuit wherein appellant resides, or has his principal place of business, or in the United States Court of Appeals for the District of Columbia.

As the House committee's report makes clear, the specific language of this bill—"fair evaluation of the entire record"—represents a new standard of judicial review, which differs from the standard of "substantial evidence on the record as a whole" that has heretofore been the criterion. The chairman of the House subcommittee that drafted and reported the bill, Hon. John Bell Williams, used the following words in explaining to the House this significant change in existing law:

Ever since the Congress began delegating regulatory functions to administrative agencies of the Government there has been disagreement among lawyers as to the fairness of the procedures under which the agencies operate. In 1946, the Administrative Procedure Act was passed in an effort to formalize the day-to-day rulemaking and regulatory procedures of Government agencies. The 1946 act provides that unless the findings of fact upon which administrative orders are based are supported by "substantial evidence" a Federal court of appeals can reverse the order of the administrative agency. Court decisions have required that an administrative agency must give consideration to the entire record, including contradictory evidence, when it determines facts.

Manufacturers of food and of food additives have manifested concern that under an administrative type of control over the use of food additives, such as is provided by H. R. 13254, it would be possible for the institutional decisions of

the Secretary of Health, Education, and Welfare to be based, for example, more upon the personal convictions of scientists employed by the Food and Drug Administration regarding the safety of an additive than upon the inferences fairly to be drawn from the scientific evidence of record. H. R. 13254 provides that orders regarding the use of food additives must "be based upon a fair evaluation of the entire record." The committee has endeavored to prescribe a new statutory criterion requiring that a high standard of fairness be observed in administrative rulemaking under this bill. Personal attitudes or preferences of administrative officials could not prevail on the basis of being supported by substantial evidence picked from the record without regard to other evidence of probative value in the record. The United States Courts of Appeals will be able to enforce this high standard by determining whether the Secretary of Health, Education, and Welfare has given appropriate consideration to the inferences which should fairly be drawn from all of the evidence of record.

Effective date

This legislation will, except as hereinafter stated, take effect on the date on which it is enacted. Thus the Food and Drug Administration can immediately begin making determinations as to the safety of food additives.

However, since it will take a certain amount of time to make these determinations of safety, the provisions of section 3 of the legislation (which will have the effect of permitting seizure, injunction suits, and criminal prosecutions on account of the shipment in interstate commerce of an additive, or food containing an additive, which has not been determined to be safe) will not take effect until 180 days after the enactment of this legislation.

A further exception is made in the case of any particular commercial use of a food additive if such use began before January 1, 1958. In the case of such use, section 3 would take effect either on the establishment of an order with respect to the safety of such use, or 18 months after the date of enactment of the legislation (unless extended by the Secretary for not more than an additional 12 months), whichever date occurs first.

Meat inspection

The bill as amended provides that nothing in this legislation shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907. This provision would leave unaffected the jurisdiction of the Department of Agriculture with respect to the use of food additives in meat or meat food products in establishments which are subject to the Meat Inspection Act.

DEPARTMENTAL REPORT

The report of the Secretary of Health, Education, and Welfare on S. 4193, sponsored by Senator Hill and Senator Smith of New Jersey, which is identical, save for the nonsubstantive amendments added

by your committee and one amendment accepted by the committee on the House of Representatives and discussed below, is as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
July 29, 1958.

HON. LISTER HILL,
*Chairman, Committee on Labor and Public Welfare,
United States Senate, Washington, D. C.*

DEAR MR. CHAIRMAN: This is in response to your request for a report on S. 4193, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

S. 4193 is in substantial agreement with S. 1895 which was drafted in this Department and submitted to the President of the Senate with our letter of April 5, 1957 (copy enclosed). The discussion of the principal features of the draft bill, which accompanied our letter of April 5, would apply in general to S. 4193.

We understand that S. 4193 is identical with H. R. 13254, the bill drafted by the House Committee on Interstate and Foreign Commerce after it held extensive hearings on food additives legislation. In our letter of July 11, 1958, to the chairman of the House Committee on Interstate and Foreign Commerce, we endorsed H. R. 13254 and it has now been reported favorably by the House committee.

S. 4193 would accomplish the public health benefits that we envisioned in drafting proposed legislation last year. We urgently recommend its enactment or the enactment of H. R. 13254 at this session of Congress.

In view of the urgency, time has not permitted the submission of this report to the Bureau of the Budget in accordance with the usual procedure.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary.

AMENDMENTS

Two amendments made by your committee to the bill as passed by the House are explained below. We would like, in addition, to call attention to the fact that the Committee on Interstate and Foreign Commerce of the House of Representatives, before bringing the bill to a vote in the House, decided to add to its previously approved bill the provision which appears on page 8 of the House-passed bill (lines 10 to 15) and reads as follows:

Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal;

Your committee, which has the responsibility in the Senate of considering all legislation primarily relating to the health of our people, is well aware and thoroughly approving of the vast amount of time and energy which Congressman Delaney, author of that amendment, has devoted to the fight against cancer and to our attempts to find its cause and cure. We have no objections to that amendment what-

soever, but we would point out that in our opinion it is the intent and purpose of this bill, even without that amendment, to assure our people that nothing shall be added to the foods they eat which can reasonably be expected to produce any type of illness in humans or animals. We applaud Congressman Delaney for having taken this, as he has every other opportunity, to focus our attention on the cancer-producing potentialities of various substances, but we want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability. In short, we believe the bill reads and means the same with or without the inclusion of the clause referred to. This is also the view of the Food and Drug Administration.

The first of the amendments added to the bill by your committee appears on page 15 as section 8 of the bill. It would increase the salary of the Commissioner of Food and Drugs from \$17,500 to \$20,000. In recommending this increase, the Department of Health, Education, and Welfare set forth its reasoning in a memorandum to the committee which we set forth herewith.

JULY 24, 1958.

MEMORANDUM TO THE COMMITTEE ON LABOR AND PUBLIC WELFARE,
UNITED STATES SENATE

SALARY OF THE COMMISSIONER OF FOOD AND DRUGS

The position of Commissioner of Food and Drugs is currently classified as GS-18, which carries a salary of \$17,500. In the light of the scope and complexity of the program administered by the Commissioner of Food and Drugs the Department of Health, Education, and Welfare believes that his salary should be increased to \$20,000.

The importance of such an increase in the salary of the Commissioner of Food and Drugs has now been accentuated by the provision of the recent Classified Pay Act under which five much-needed scientific supergrade positions have been assigned to the Food and Drug Administration. Two of these positions will carry salaries higher than the current salary of the Commissioner; three will carry the same salary.

Statutory language to provide for the proposed increase is attached.

ELLIOT L. RICHARDSON,
Assistant Secretary.

Your committee not only agrees with the Department but also believes the recommended action to be long overdue. We unanimously recommend its approval.

The second amendment adopted by the committee has to do with key personnel attached to the National Institutes of Health. It appears as section 9 on page 15 of the bill. It does not change the maximum salary limitations under that section of the act it amends, nor does it increase the total number of supergrade positions allocated by the Congress to the National Institutes of Health. It merely clarifies the intent of the Congress that, just as in the case of the recently enacted National Aeronautics and Space Act in which that intent was explicitly set forth, so too in the case of the National Insti-

tutes of Health do we intend to permit the employment in these key positions of men with superior executive and administrative skills as well as men with superior scientific and professional skills.

CHEMICAL PRESERVATIVES

During the committee's deliberations on this measure, Senator Goldwater questioned Commissioner Larrick of the Food and Drug Administration concerning the Department's policies and regulations with respect to preservatives which might be added to cantaloups and other produce of the soil after harvesting. While those questions are the subject of other legislation already on the statute books and do not relate to the measure before us, the committee believes that the explanation given by Commissioner Larrick concerning current law, policies, and regulations bearing on that problem may well be of interest to individuals concerned with any aspect of legislation dealing with the safety of foodstuffs. Therefore, and in response to Senator Goldwater's request, the committee is happy to include in this report that confirmatory letter sent by Commissioner Larrick to the chairman of this committee which sums up the Commissioner's replies to Senator Goldwater's questions. It is as follows:

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 15, 1958.

HON. LISTER HILL,

*Chairman, Committee on Labor and Public Welfare,
United States Senate, Washington, D. C.*

DEAR MR. CHAIRMAN: This confirms the statement I made today before the Committee on Labor and Public Welfare in response to questions by Senator Goldwater about the required declaration of the presence and the names of chemical preservatives on cantaloups and other produce of the soil.

Cantaloups and other produce of the soil are not required to have a sticker label on them for this purpose. If they are treated with a pesticide chemical after harvest to prevent deterioration, it is enough that the shipping container has a label giving this information. If the cantaloups are taken away from the containers for retail sales display, all we require is that there be a counter card containing the information. Each melon need not be marked.

Pesticide chemicals applied before harvest are used under spray schedules and other safeguards developed by the Department of Agriculture and disseminated by the county agents, and by labeling on the pesticides themselves. Since the packing-shed operator ordinarily has no means of knowing what pesticides may have been used in growing all the fruit he buys, we have issued an exempting regulation recognizing that it is impractical for him to label fruit with information as to the preharvest treatment. We could not extend this exemption to postharvest treatments because we could not make the statutory finding that the label declaration was impractical.

We have recognized that it may be impractical in the retail store to name on the counter card the pesticides on citrus fruit, and have proposed a regulation to require that the counter card have only the

information that a preservative has been used, but not the name of the preservative.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

AN ACT To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * * * *

(s) *The term “food additive” means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—*

“(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

(t) *The term “safe”, as used in paragraph (s) of this section and in section 409, has reference to the helath of man or animal.*

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

* * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, or 704 concerning any method or process which as a trade secret is entitled to protection.

* * * * *

CHAPTER IV—FOOD

* * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance, **[except]** (*except a pesticide chemical in or on a raw agricultural commodity, and except a food additive*) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section **[408 (a)]** 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity*; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally

subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

* * * * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) (A) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) (A) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

* * * * *

FOOD ADDITIVES

Unsafe Food Additives

SEC. 409. (a) *A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—*

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

Petition To Establish Safety

(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Action on the Petition

(c) (1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) *No such regulation shall issue if a fair evaluation of the data before the Secretary—*

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) *If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitations is required in order to assure that the proposed use of an additive will be safe, the Secretary—*

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) *In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—*

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

Regulation Issued on Secretary's Initiative

(d) *The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.*

Publication and Effective Date of Orders

(e) *Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).*

Objections and Public Hearing

(f) (1) *Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing, for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.*

(2) *Such order shall be based upon a fair valuation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.*

(3) *The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.*

Judicial Review

(g) (1) *In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any persons who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.*

(2) *A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section*

(3) *The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.*

(4) *If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.*

(5) *The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.*

Amendment or Repeal of Regulations

(h) *The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.*

Exemptions for Investigational Use

(i) *Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.*

PUBLIC HEALTH SERVICE ACT, AS AMENDED (42 U. S. C. 310 (g))

* * * * *

SEC. 208.

* * * * *

(g) The Secretary is authorized to establish and fix the compensation for, within the Public Health Service, not more than eighty-five positions of which not less than seventy-three shall be for the National Institutes of Health in the professional, [and] scientific, *and executive* service, each such position being established to effectuate those research and development activities of the Public Health Service which require the services of specially qualified scientific, [or] professional, *and administrative* personnel: *Provided*, That the rates of compensation for positions established pursuant to the provisions of this subsection shall not be less than \$12,500 per annum nor more than \$19,000 per annum, and shall be subject to the approval of the Civil Service Commission. Positions created pursuant to this subsection shall be included in the classified civil service of the United States but appointment to such positions shall be made without competitive examination upon approval of the proposed appointee's qualification by the Civil Service Commission or such officers and agents as it may designate for this purpose.

○

85TH CONGRESS
2D SESSION

H. R. 13254

IN THE SENATE OF THE UNITED STATES

AUGUST 14, 1958

Read twice and referred to the Committee on Labor and Public Welfare

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Food Additives Amend-
4 ment of 1958".

5 SEC. 2. Section 201, as amended, of the Federal Food,
6 Drug, and Cosmetic Act is further amended by adding at
7 the end of such section the following new paragraphs:

8 “(s) The term ‘food additive’ means any substance the
9 intended use of which results or may reasonably be expected

1 to result, directly or indirectly, in its becoming a component
2 or otherwise affecting the characteristics of any food (includ-
3 ing any substance intended for use in producing, manufac-
4 turing, packing, processing, preparing, treating, packaging,
5 transporting, or holding food; and including any source of
6 radiation intended for any such use), if such substance is not
7 generally recognized, among experts qualified by scientific
8 training and experience to evaluate its safety, as having been
9 adequately shown through scientific procedures (or, in the
10 case of a substance used in food prior to January 1, 1958,
11 through either scientific procedures or experience based on
12 common use in food) to be safe under the conditions of its
13 intended use; except that such term does not include—

14 “(1) a pesticide chemical in or on a raw agricultural
15 commodity; or

16 “(2) a pesticide chemical to the extent that it is
17 intended for use or is used in the production, storage, or
18 transportation of any raw agricultural commodity; or

19 “(3) any substance used in accordance with a sanc-
20 tion or approval granted prior to the enactment of this
21 paragraph pursuant to this Act or the Meat Inspection
22 Act of March 4, 1907 (34 Stat. 1260), as amended and
23 extended (21 U. S. C. 71 and the following).

24 “(t) The term ‘safe’, as used in paragraph (s) of this

1 section and in section 409, has reference to the health of man
2 or animal.”

3 SEC. 3. (a) Clause (2) of section 402 (a), as amended,
4 of such Act is amended to read as follows: “(2) (A) if it
5 bears or contains any added poisonous or added deleterious
6 substance (except a pesticide chemical in or on a raw agri-
7 cultural commodity and except a food additive) which is un-
8 safe within the meaning of section 406, or (B) if it is a
9 raw agricultural commodity and it bears or contains a pesti-
10 cide chemical which is unsafe within the meaning of section
11 408 (a), or (C) if it is, or it bears or contains, any food
12 additive which is unsafe within the meaning of section 409:
13 *Provided*, That where a pesticide chemical has been used in
14 or on a raw agricultural commodity in conformity with an
15 exemption granted or a tolerance prescribed under section
16 408 and such raw agricultural commodity has been subjected
17 to processing such as canning, cooking, freezing, dehydrat-
18 ing, or milling, the residue of such pesticide chemical remain-
19 ing in or on such processed food shall, notwithstanding the
20 provisions of sections 406 and 409, not be deemed unsafe if
21 such residue in or on the raw agricultural commodity has been
22 removed to the extent possible in good manufacturing prac-
23 tice and the concentration of such residue in the processed

1 food when ready to eat is not greater than the tolerance
2 prescribed for the raw agricultural commodity;”.

3 (b) Section 402 (a) , as amended, of such Act is further
4 amended by striking out the period at the end thereof and
5 inserting in lieu thereof a semicolon and the following: “or
6 (7) if it has been intentionally subjected to radiation, unless
7 the use of the radiation was in conformity with a regulation
8 or exemption in effect pursuant to section 409.”

9 (c) The first sentence of section 406 (a) of such
10 Act is amended by striking out “clause (2)” wherever it
11 appears in such sentence and inserting in lieu thereof “clause
12 (2) (A)”.

13 SEC. 4. Chapter IV of such Act is amended by adding
14 at the end thereof the following new section:

15 “FOOD ADDITIVES

16 “Unsafe Food Additives

17 “SEC. 409. (a) A food additive shall, with respect to
18 any particular use or intended use of such additives, be
19 deemed to be unsafe for the purposes of the application
20 of clause (2) (C) of section 402 (a) , unless—

21 “(1) it and its use or intended use conform to the
22 terms of an exemption which is in effect pursuant to sub-
23 section (i) of this section; or

24 “(2) there is in effect, and it and its use or
25 intended use are in conformity with, a regulation issued

under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

“Petition To Establish Safety

“(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

“(2) Such petition shall, in addition to any explanatory or supporting data, contain—

“(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

“(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

“(C) all relevant data bearing on the physical or other technical effect such additive is intended to pro-

1 duce, and the quantity of such additive required to
2 produce such effect;

3 “(D) a description of practicable methods for deter-
4 mining the quantity of such additive in or on food, and
5 any substance formed in or on food, because of its use;
6 and

7 “(E) full reports of investigations made with re-
8 spect to the safety for use of such additive, including full
9 information as to the methods and controls used in con-
10 ducting such investigations.

11 “(3) Upon request of the Secretary, the petitioner shall
12 furnish (or, if the petitioner is not the manufacturer of such
13 additive, the petitioner shall have the manufacturer of such
14 additive furnish, without disclosure to the petitioner) a full
15 description of the methods used in, and the facilities and
16 controls used for, the production of such additive.

17 “(4) Upon request of the Secretary, the petitioner shall
18 furnish samples of the food additive involved, or articles used
19 as components thereof, and of the food in or on which the
20 additive is proposed to be used.

21 “(5) Notice of the regulation proposed by the petitioner
22 shall be published in general terms by the Secretary within
23 thirty days after filing.

1 “Action on the Petition

2 “(c) (1) The Secretary shall—

3 “(A) by order establish a regulation (whether or
4 not in accord with that proposed by the petitioner)
5 prescribing, with respect to one or more proposed uses
6 of the food additive involved, the conditions under which
7 such additive may be safely used (including, but not lim-
8 ited to, specifications as to the particular food or classes
9 of food in or in which such additive may be used, the
10 maximum quantity which may be used or permitted to
11 remain in or on such food, the manner in which such
12 additive may be added to or used in or on such food, and
13 any directions or other labeling or packaging require-
14 ments for such additive deemed necessary by him to as-
15 sure the safety of such use), and shall notify the peti-
16 tioner of such order and the reasons for such action; or

17 “(B) by order deny the petition, and shall notify
18 the petitioner of such order and of the reasons for such
19 action.

20 “(2) The order required by paragraph (1) (A) or
21 (B) of this subsection shall be issued within ninety days
22 after the date of filing of the petition, except that the Secre-

1 tary may (prior to such ninetieth day), by written notice
2 to the petitioner, extend such ninety-day period to such
3 time (not more than one hundred and eighty days after the
4 date of filing of the petition) as the Secretary deems neces-
5 sary to enable him to study and investigate the petition.

6 “(3) No such regulation shall issue if a fair evaluation
7 of the data before the Secretary—

8 “(A) fails to establish that the proposed use of the
9 food additive, under the conditions of use to be speci-
10 fied in the regulation, will be safe: *Provided*, That no
11 additive shall be deemed to be safe if it is found to in-
12 duce cancer when ingested by man or animal, or if it
13 is found, after tests which are appropriate for the evalua-
14 tion of the safety of food additives, to induce cancer
15 in man or animal; or

16 “(B) shows that the proposed use of the additive
17 would promote deception of the consumer in violation
18 of this Act or would otherwise result in adulteration
19 or in misbranding of food within the meaning of this Act.

20 “(4) If, in the judgment of the Secretary, based upon
21 a fair evaluation of the data before him, a tolerance limita-
22 tion is required in order to assure that the proposed use
23 of an additive will be safe, the Secretary—

24 “(A) shall not fix such tolerance limitation at a
25 level higher than he finds to be reasonably required to

1 accomplish the physical or other technical effect for
2 which such additive is intended; and

3 “(B) shall not establish a regulation for such pro-
4 posed use if he finds upon a fair evaluation of the data
5 before him that such data do not establish that such use
6 would accomplish the intended physical or other techni-
7 cal effect.

8 “(5) In determining, for the purposes of this section,
9 whether a proposed use of a food additive is safe, the Sec-
10 retary shall consider among other relevant factors—

11 “(A) the probable consumption of the additive
12 and of any substance formed in or on food because of
13 the use of the additive;

14 “(B) the cumulative effect of such additive in the
15 diet of man or animals, taking into account any chemi-
16 cally or pharmacologically related substance or sub-
17 stances in such diet; and

18 “(C) safety factors which in the opinion of experts
19 qualified by scientific training and experience to evaluate
20 the safety of food additives are generally recognized as
21 appropriate for the use of animal experimentation data.

22 “Regulation Issued on Secretary’s Initiative

23 “(d) The Secretary may at any time, upon his own
24 initiative, propose the issuance of a regulation prescribing,

1 with respect to any particular use of a food additive, the
2 conditions under which such additive may be safely used,
3 and the reasons therefor. After the thirtieth day following
4 publication of such a proposal, the Secretary may by order
5 establish a regulation based upon the proposal.

6 "Publication and Effective Date of Orders

7 "(e) Any order, including any regulation established
8 by such order, issued under subsection (c) or (d) of this
9 section, shall be published and shall be effective upon publi-
10 cation, but the Secretary may stay such effectiveness if, after
11 issuance of such order, a hearing is sought with respect to
12 such order pursuant to subsection (f).

13 "Objections and Public Hearing

14 "(f) (1) Within thirty days after publication of an
15 order made pursuant to subsection (c) or (d) of this
16 section, any person adversely affected by such an order may
17 file objections thereto with the Secretary, specifying with
18 particularity the provisions of the order deemed objection-
19 able, stating reasonable grounds therefor, and requesting a
20 public hearing upon such objections. The Secretary shall,
21 after due notice, as promptly as possible hold such public
22 hearing for the purpose of receiving evidence relevant and
23 material to the issues raised by such objections. As soon as
24 practicable after completion of the hearing, the Secretary

1 shall by order act upon such objections and make such order
2 public.

3 “(2) Such order shall be based upon a fair evaluation
4 of the entire record at such hearing, and shall include a
5 statement setting forth in detail the findings and conclusions
6 upon which the order is based.

7 “(3) The Secretary shall specify in the order the date
8 on which it shall take effect, except that it shall not be
9 made to take effect prior to the ninetieth day after its
10 publication, unless the Secretary finds that emergency con-
11 ditions exist necessitating an earlier effective date, in which
12 event the Secretary shall specify in the order his findings as
13 to such conditions.

14 “Judicial Review

15 “(g) (1) In a case of actual controversy as to the
16 validity of any order issued under subsection (f), including
17 any order thereunder with respect to amendment or repeal
18 of a regulation issued under this section, any person who will
19 be adversely affected by such order may obtain judicial
20 review by filing in the United States Court of Appeals for
21 the circuit wherein such person resides or has his principal
22 place of business, or in the United States Court of Appeals
23 for the District of Columbia Circuit, within sixty days after

1 the entry of such order, a petition praying that the order
2 be set aside in whole or in part.

3 “(2) A copy of such petition shall be forthwith served
4 upon the Secretary, or upon any officer designated by him
5 for that purpose, and thereupon the Secretary shall certify
6 and file in the court a transcript of the proceedings and the
7 record on which he based his order. Upon such filing, the
8 court shall have exclusive jurisdiction to affirm or set aside
9 the order complained of in whole or in part. The findings
10 of the Secretary with respect to questions of fact shall be
11 sustained if based upon a fair evaluation of the entire record
12 at such hearing. The court shall advance on the docket and
13 expedite the disposition of all causes filed therein pursuant
14 to this section.

15 “(3) The court, on such judicial review, shall not sustain
16 the order of the Secretary if he failed to comply with any
17 requirement imposed on him by subsection (f) (2) of this
18 section.

19 “(4) If application is made to the court for leave to
20 adduce additional evidence, the court may order such addi-
21 tional evidence to be taken before the Secretary and to be
22 adduced upon the hearing in such manner and upon such
23 terms and conditions as to the court may seem proper, if
24 such evidence is material and there were reasonable grounds
25 for failure to adduce such evidence in the proceedings below.

1 The Secretary may modify his findings as to the facts and
2 order by reason of the additional evidence so taken, and
3 shall file with the court such modified findings and order.

4 “(5) The judgment of the court affirming or setting
5 aside, in whole or in part, any order under this section shall
6 be final, subject to review by the Supreme Court of the
7 United States upon certiorari or certification as provided
8 in section 1254 of title 28 of the United States Code. The
9 commencement of proceedings under this section shall not,
10 unless specifically ordered by the court to the contrary,
11 operate as a stay of an order.

12 “Amendment or Repeal of Regulations

13 “(h) The Secretary shall by regulation prescribe the
14 procedure by which regulations under the foregoing pro-
15 visions of this section may be amended or repealed, and
16 such procedure shall conform to the procedure provided
17 in this section for the promulgation of such regulations.

18 “Exemptions for Investigational Use

19 “(i) Without regard to subsections (b) to (h), inclu-
20 sive, of this section, the Secretary shall by regulation provide
21 for exempting from the requirements of this section any
22 food additive, and any food bearing or containing such addi-
23 tive, intended solely for investigational use by qualified ex-
24 perts when in his opinion such exemption is consistent with
25 the public health.”

1 SEC. 5. Section 301 (j) of such Act is amended by
2 inserting "409," after "404,".

3 SEC. 6. (a) Except as provided in subsections (b) and
4 (c) of this section, this Act shall take effect on the date of
5 its enactment.

6 (b) Except as provided in subsection (c) of this sec-
7 tion, section 3 of this Act shall take effect on the one hun-
8 dred and eightieth day after the date of enactment of this
9 Act.

10 (c) With respect to any particular commercial use of a
11 food additive, if such use was made of such additive before
12 January 1, 1958, section 3 of this Act shall take effect—

13 (1) either (A) one year after the effective date
14 established in subsection (b) of this section, or (B) at
15 the end of such additional period (but not later than
16 two years from such effective date established in sub-
17 section (b)) as the Secretary of Health, Education, and
18 Welfare may prescribe on the basis of a finding that
19 such extension involves no undue risk to the public
20 health and that conditions exist which necessitate the
21 prescribing of such an additional period, or

22 (2) on the date on which an order with respect to
23 such use under section 409 of the Federal Food, Drug,
24 and Cosmetic Act becomes effective,
25 whichever date first occurs.

1 SEC. 7. Nothing in this Act shall be construed to exempt
2 any meat or meat food product or any person from any
3 requirement imposed by or pursuant to the Meat Inspection
4 Act of March 4, 1907, 34 Stat. 1260, as amended and
5 extended (21 U. S. C. 71 and the following).

Passed the House of Representatives August 13, 1958.

Attest:

RALPH R. ROBERTS,

Clerk.

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

AUGUST 14, 1958

Read twice and referred to the Committee on Labor
and Public Welfare

Aug. 20, 1958

- 3 -

11. RESEARCH. Passed with an amendment S. 3268, to amend the National Science Foundation Act regarding certain authority of the Board. The House amendment substitutes the text of H. R. 11257, a similar bill. pp. 17281-2
12. FOREIGN TRADE. Rep. Sikes urged the establishment of an Inter-American Bank designed to promote trade and improve the prosperity of the nations of the Western Hemisphere. p. 17299
13. LEGISLATIVE PROGRAM. Agreed to a unanimous consent request by Rep. Albert that for the remainder of this week bills may be considered under suspension of the rules. pp. 17289-90

SENATE

14. PERSONNEL. Conferees were appointed on H. R. 7710, to provide for the lump-sum payment of all accumulated and accrued annual leave of deceased employees. House conferees have been appointed. p. 17323
Passed without amendment H. R. 9407, to provide additional opportunity for certain Government employees to obtain career-conditional and career appointments in the competitive civil service. This bill will now be sent to the President. p. 17170
Sen. Martin, Pa., was appointed a conferee on S. 25 to specify the effective date upon which pay changes of wage-board employees shall begin following start of a survey. p. 17323
15. FOOD ADDITIVES. At the request of Sen. Clark passed over H. R. 13254, to prohibit the use of food additives until after adequate tests of their safety, which had been placed at the end of the calendar earlier in the day at the request of Sen. Carroll for Sen. O'Mahoney. pp. 17171, 17166
16. MONOPOLIES. Sen. Wiley submitted an amendment to H. R. 2, the Illinois Waterway - Great Lakes diversion bill, which would limit the use of good faith as a defense under Clayton Act prosecutions for price discrimination. p. 17146
17. FORESTRY. Sen. Humphrey inserted resolutions from the villages of McKinly and Stuntz, Minn., urging construction of projects planned for the Superior National Forest so as to provide employment in that area. p. 17144
18. ECONOMIC SITUATION. Sen. Martin, Pa., discussed the economic situation and the dangers of inflation. He cited figures on U. S. Steel Corp. which he asserted showed that price increases were proportionate to the prior wage increases and thus proved the existence of wage-cost-push inflation in recent years. pp. 17156-9

ITEMS IN APPENDIX

19. WITHHOLDING INFORMATION. Extension of remarks of Rep. Moss discussing the signing by the President of H. R. 2767, with respect to the authority of Federal officers and agencies to withhold information and limit the availability of records, and inserting an analysis of the "absurdity and the dangers of this Government-wide claim of 'executive privilege'" pp. A7448-50
20. FARM PROGRAM. Rep. Derounian commended and inserted Secretary Benson's magazine article, "Don't Let Unpopularity Scare You." pp. A7466-7

21. MINERALS. Extension of remarks of Rep. Dixon inserting a table showing the maximum costs of incentive payments proposed by S. 4036, the minerals stabilization bill. pp. A7472-3
22. TAXATION. Extension of remarks of Rep. Sadlak reemphasizing his belief that a thoroughgoing reform of our Federal income tax rate structure is vital to our national security. pp. A7479-81
23. AREA DEVELOPMENT. Speech in the House by Rep. Roosevelt urging passage of S. 3683, the proposed area redevelopment bill. pp. A7488-9
24. HUMANE SLAUGHTER. Sen. Proxmire inserted an editorial commending Sen. Humphrey for his "great fight" in securing passage of the humane-slaughter bill. pp. A7494-5

BILL APPROVED BY THE PRESIDENT

25. LAND TRANSFER. H. R. 11800, which authorizes the Secretary to convey approximately 7 acres of the land and improvements comprising the U. S. Animal Quarantine Station to the city of Clifton, N. J., for public use purposes, subject to the city paying 75 percent of the appraised value of the land and improvements, plus \$30,000 to be available to the Department in making alterations and improvements on the remaining portion of the quarantine station. Approved August 20, 1958 (Public Law 85-687, 85th Congress).

RETIREMENT OF MAJ. GEN. CHARLES G. HOLLE

Mr. LONG. Mr. President, during the month of October of this year, Maj. Gen. Charles G. Holle will retire from the service of the Corps of Engineers of the United States Army—more than 40 years from the date he entered the United States Military Academy as a cadet. For 40 years General Holle has been a faithful servant, rendering devoted service to the United States Army in many capacities. I came to know him best when he was district engineer of the New Orleans district, in charge of the flood-control and navigation programs of my State.

General Holle served the New Orleans district of the Corps of Engineers for nearly 4 years—one of the longest periods of commissioned service in the history of that district. During that time he won the hearts of his employees, of the officials of the city of New Orleans and the State of Louisiana, and of the man on the street who knew him as a man devoted to his job and to the mission for which he was held responsible.

The district engineer at New Orleans holds a difficult, a strategic, and an important job. The job is difficult because the incumbent in that job must wear many hats—he must be able to meet and satisfy the needs of people in many walks of life; it is strategic because New Orleans is dependent for its existence upon its waterways and the man who administers them holds the key to many of the problems that perennially present themselves; it is important because the decisions he makes are far reaching and have a bearing on the lives of many people who live behind the levees that protect one of the Nation's fastest growing metropolitan areas.

I do not believe that any man graced that job with more dignity than did Charles G. Holle. During his tour of duty with the engineers he distinguished himself on many other assignments. Some of them were:

Three tours of duty in the Canal Zone.
Two assignments on flood-control duties.

Foreign duty.

Division engineer duty.

Five important assignments in the Office of the Chief of Engineers.

There are times when we regret the regulations that require a man to retire when he reaches a designated age. This is one of those times. As everyone who knows him will attest, upon his retirement, General Holle is strenuous, vigorous, forceful, and capable, and is performing his usual outstanding job. His capable guidance will be missed by many who look to him for advice. At the present time, he is filling 4 jobs in an outstanding manner—he is special assistant to the Chief of Engineers for St. Lawrence matters; he is alternate for the Secretary of the Army on the St. Lawrence River Joint Board of Engineers; he is Chairman of the Board of Engineers for Rivers and Harbors; he is president of the Beach Erosion Board.

I am not expressing my views alone. These are the views of other members of the delegation of the State of Louisiana who worked with and who respect

the judgment and the ability of General Holle.

Mr. President, I make this statement for the RECORD, in order that the Members of this body may know the esteem in which we hold Maj. Gen. Charles G. Holle, and in order that we may use this means of expressing our appreciation to a man who has devoted his life to public service and who has accomplished so much. I hope that his zeal will be an incentive for many to follow in the future, and I hope that he will continue his work in a civilian capacity, for he has demonstrated to us that he has reached the point in his life where we need him most.

Mr. LAUSCHE. Mr. President, on July 21 last the Standard Oil Co. of Ohio put into effect a 1-cent-per-gallon increase in its regular gasoline sold at Sohio service stations. Within the next day or two, all of the other major brands also raised their gas prices the same amount.

Based on published figures on sales, the Standard Oil Co. of Ohio stands to gain some additional \$10 million a year in the State of Ohio due to this increase. Counting the increase applied by all companies, the cost to the Ohio consumers will be some \$31 million during the next year.

As far as I can determine, this increase is not justified. Even counting a wage increase granted the employees of Standard Oil of Ohio, this would amount to only about 25 percent of the increase. In addition, some crude oil prices are dropping; and inventories are at a normal 4 weeks supply, which means the oil companies cannot claim that a shortage has brought the price increase. As a matter of fact, Standard of Ohio and the other companies showed a drop in sales during the first half of this year.

Mr. President, this pattern of rising prices in the face of decreasing production and sales is the same pattern that we see in so many other industries. In steel, for instance, the recent price increase was effective as soon as the United States Steel Corp. joined the parade of higher prices. In Ohio, one company again takes the lead—Standard of Ohio—and the others fall into line.

It would appear logical that when sales fall, companies would try to cut prices to encourage consumers to buy. Instead, the opposite is the case in steel, in oil, and other industries.

RIISING PRICES AND FALLING PRODUCTION

It does not matter what is the cause of this trend—whether price rises are caused by wage increases, or the other way around. The situation that faces us today is that giant companies in industry after industry are raising prices higher and higher at will. The consumer apparently has nothing to say about it. He must go along, if he needs the product. This is an unhealthy situation; it means that monopoly and lack of competition have reached an alarming stage.

Leaders of industry must take action to reassure the American consumer that they are not simply out to charge all the market will bear. If they sit idly by and prices continue to rise, it will mean the ruin of the American economy.

INTEGRATION AND EDUCATION

Mr. FULBRIGHT. Mr. President, there appeared in today's Wall Street Journal an excellent editorial comment on the school situation in my State. It expresses a tolerant and understanding attitude with respect to the problems we face in Arkansas. It would be of great benefit to the people of Arkansas if more people would take this enlightened and understanding approach to the grave problem with which we are confronted.

I ask unanimous consent, Mr. President, that the editorial entitled "Integration and Education" be printed in the body of the RECORD.

There being no objection, the editorial was ordered to be printed in the RECORD, as follows:

INTEGRATION AND EDUCATION

Among the many trials of the people of Little Rock, certainly not the least of them has been the way in which the course of events has been suddenly reversed and reversed again by the various agencies of Government. And now they are to suffer more of it.

First there was the ruling of the Supreme Court that upset the old order in the schools. To this change the local authorities in Little Rock, and most of its people, tried to adjust. But then of a sudden they were confronted with troops sent by their Governor to block integration and troops sent by their President to enforce integration. Next there was a ruling by a Federal district judge denying a stay and ordering immediate integration. This was followed by an order from another Federal judge in the same district granting the people a time's respite by postponing integration.

This week the Federal circuit judges once more reversed direction. They ordered integration forthwith. Yet still nothing is settled. There is talk of another appeal to the Supreme Court, which could again reverse events, and of a special session of the legislature at which the Governor may try again to take events in his own hands.

This surely is a terrible buffeting of one people by the laws and the powers of office. Each of these officeholders may have had the right to act as he did; certainly one district judge is not bound by another. But just the same the result has been that the people of Little Rock did not know from 1 day until the next under what order of society they must live but found all changed by which holder of what office wielded the moment's power.

We cannot know what will happen next month in the schools of Little Rock. It may be too late now for the hope that somehow time and forbearance will be allowed to heal passions. And yet it must be hoped.

For any man can see what will happen if the issue of integration comes to devour the issue of education. What kind of education can we give any children, white or Negro, in classrooms inflamed by animosities or, if once more it comes to that, echoing the tramp of soldiers?

The PRESIDING OFFICER. Is there further morning business? If not, morning business is closed.

PROVISION OF NOTICE OF APPEAL FOR INTERLOCUTORY RELIEF AGAINST ORDERS OF CERTAIN ADMINISTRATIVE AGENCIES

The PRESIDING OFFICER (Mr. MORTON in the chair). The Chair lays before the Senate the unfinished business, which will be read.

The LEGISLATIVE CLERK. A bill (H. R. 6789) to provide for reasonable notice of applications to the United States courts of appeals for interlocutory relief against the orders of certain administrative agencies.

TRIBUTE TO RETIRING SENATORS

Mr. REVERCOMB. Mr. President, as we move toward the close of the sessions of the 85th Congress, I want to express my feelings and pay tribute to six Members of the Senate who, by their own choice, are voluntarily retiring from this body. With the termination of their service here, the country will suffer a distinct loss. On some public issues and on the best course of government in guiding the destiny of our Nation there have been disagreements among them. These disagreements were earnest. But they have basic traits with which all of them are endowed and which have made them towers of strength in the affairs of the Nation. They are patriotic. They are sincere. They have understanding, and a sense of fairness. They have proved themselves to be men of courage and great capacity for comprehending the problems that have confronted us during the years they have served the American people in the United States Senate.

To me, and I believe to others, they have been a source of inspiration to those who know them and have worked with them.

Our selected Republican leader who serves now as minority leader and has served as majority leader of the Senate, the Senator from California, Mr. WILLIAM F. KNOWLAND, will always be remembered as a man gifted with able leadership. He has been a pillar of strength to the Republican Party, and few men have exerted greater influence in shaping the legislation of this country during the 14 years he has served here. It is natural in him to fight for his convictions. His frank and forthright stand on public issues has gained the admiration of the American people. While one may differ with his views and conclusions, no man questions his sincerity. He leaves the Senate for the seat of the governorship of the great State of California, and he goes with my wishes for complete success.

My neighboring State of Pennsylvania loses a distinguished Member of the Senate through his choice to retire this year. Earlier today I had occasion to speak here upon the departure of EDWARD MARTIN from the Senate. No man in public life today has achieved more, or rendered finer service to the country to which he is devoted. A great soldier in the time of our wars; Governor of Pennsylvania; an outstanding Member of the United States Senate; EDWARD MARTIN retires from this body with the acclaim of its Members and his country.

In the retirement of our colleague, WILLIAM JENNER, of Indiana, we lose the services of a courageous patriot and statesman. No man has been more forceful in defending the interest of America both upon the fields of battle

and in the Halls of Congress than JENNER, of Indiana. He does not hesitate to stand forth for those things in which he earnestly believes. However much others may differ with him, they know that he fights for those principles he believes to be right.

The distinguished senior Senator from New Jersey, H. ALEXANDER SMITH, able and diligent, leaves this body with the respect of every Member. A patriot and a scholar, his influence has for years been felt in the deliberations and conclusions of the Senate of the United States. He retires to the cloisters of Princeton University from whence he came to give his country his able services.

The State of New York, is losing a great public servant and the country is likewise losing a statesman of high caliber in the retiring of IRVING M. IVES, of New York. A tireless worker with a scholarly mind and a deep understanding of the complex problems of this industrial age, he has set an example of earnestness and outstanding statesmanship. His sense of fairness in dealing with controversies, ever the servant, have left a high example and a lasting mark upon the Senate.

Senator RALPH FLANDERS, of Vermont, has contributed much to the deliberations and work of this Senate. Gifted with a scholarly mind and the experience of successful business, he has had this rare combination of attributes so useful in meeting the problems that a fast changing age has brought.

I express to each of them my best wishes for happiness and continued high success in the years ahead. They have demonstrated their greatness. The need of their guidance in the life of the Nation still exists, and it is my hope that they will return here often to give us the benefit of their experience and their wisdom.

May their years be happy ones. This they richly deserve through the service that they have rendered their country and their fellow man.

Mr. MARTIN of Pennsylvania. Mr. President, I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The Chief Clerk proceeded to call the roll.

Mr. MARTIN of Pennsylvania. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER (Mr. COTTON in the chair). Without objection, it is so ordered.

THE CALENDAR

The PRESIDING OFFICER. Under the order previously entered, the clerk will call the measures on the calendar, starting with Order No. 2484, H. R. 12365.

SUCK PIL RA

The bill (H. R. 12365) for the relief of Suck Pil Ra was considered, ordered to a third reading, read the third time, and passed.

PROHIBITION OF USE OF UNTESTED ADDITIVES IN FOOD— BILL PASSED TO FOOT OF CALENDAR

The bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, was announced as next in order.

Mr. MORTON. Mr. President, I ask that the bill go to the foot of the calendar.

The PRESIDING OFFICER. The bill will go to the foot of the calendar.

Mr. CARROLL subsequently said: Mr. President, a parliamentary inquiry.

The PRESIDING OFFICER. The Senator will state it.

Mr. CARROLL. I should like to know what action has been taken on Calendar No. 2487, H. R. 13254.

The PRESIDING OFFICER. That bill was passed to the foot of the calendar.

Mr. CARROLL. The Senator from Wyoming [Mr. O'MAHONEY] is not present this morning. He is attending a funeral. He has asked that his specific objection be recorded on this bill. A very important amendment has been offered recently, within the last 30 minutes. The matter has been under investigation. Hearings have been held by our committee for a period of time on the matter. I am confident the chairman of the subcommittee, the Senator from Tennessee [Mr. KEFAUVER], and the Senator from Wyoming [Mr. O'MAHONEY], would register a vigorous objection to Order No. 2487, House bill 13254, as now amended.

The PRESIDING OFFICER. Does the Senator desire to have the order placing the bill at the foot of the calendar rescinded?

Mr. CARROLL. The majority leader has informed me that the bill has gone to the foot of the calendar.

VALIDATION OF OVERPAYMENTS TO CERTAIN OFFICERS OF ARMED SERVICES

The Senate proceeded to consider the bill (H. R. 3366) to validate overpayments and pay and allowances made to certain officers of the Army, Navy, Naval Reserve, and Air Force, which had been reported from the Committee on the Judiciary, with amendments, on page 1, line 8, after the word "hospital", to strike out "received compensation from that hospital (including meals and living quarters in kind)", and on page 2, line 5, after the word "as", to insert "such compensation."

The amendments were agreed to. The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

COOPER TIRE & RUBBER CO.

The bill (H. R. 7499) for the relief of the Cooper Tire & Rubber Co. was con-

There being no objection, the Senate proceeded to consider the bill (H. R. 13500), to provide for the disposal of federally owned property of the Hanson, Company, and Houma Canals, La., and for other purposes.

The PRESIDING OFFICER. If there be no amendment to be proposed, the question is on the third reading of the bill.

The bill (H. R. 13500) was ordered to a third reading, read the third time, and passed.

The PRESIDING OFFICER. Without objection, S. 4198 is indefinitely postponed.

RECOMMENDATIONS FOR LEGISLATION FOR REIMBURSEMENT TO STATES FOR CERTAIN HIGHWAYS

The joint resolution (H. J. Res. 654) requiring the Secretary of Commerce to submit certain recommendations for legislation for the purpose of assisting Congress to determine whether or not to reimburse States for certain highways on the National System of Interstate and Defense Highways was considered, ordered to a third reading, read the third time, and passed.

The PRESIDING OFFICER. Without objection, the preamble is agreed to.

BILL PASSED OVER

The bill (H. R. 12728) to amend the Longshoremen's and Harbor Workers' Compensation Act, with respect to the payment of compensation in cases where third persons are liable, was announced as next in order.

Mr. CLARK. Over, Mr. President.

The PRESIDING OFFICER. The bill will be passed over.

HARRY N. DUFF

Mr. CLARK. Mr. President, I ask unanimous consent that the Senate return to the consideration of Calendar No. 2407, H. R. 1695, for the relief of Harry N. Duff. I believe the bill was objected to because there was no amendment offered. I understand the distinguished Senator from Mississippi desires to offer an amendment at this point.

The PRESIDING OFFICER. Is there objection to the request of the Senator from Pennsylvania?

There being no objection, the Senate proceeded to consider the bill (H. R. 1695) for the relief of Harry N. Duff.

Mr. EASTLAND. Mr. President, I offer an amendment and ask that it be stated.

The PRESIDING OFFICER. The amendment will be stated for the information of the Senate.

The LEGISLATIVE CLERK. On page 1, in line 10, it is proposed to insert the following:

The enactment of this act shall not be construed as any inference of liability on the part of the Government of the United States.

The PRESIDING OFFICER. The question is on agreeing to the amendment offered by the Senator from Mississippi.

The amendment was agreed to.

The PRESIDING OFFICER. The question is on the engrossment of the amendment and third reading of the bill.

The amendment was ordered to be engrossed and the bill to be read a third time.

The bill (H. R. 1695) was read the third time, and passed.

MRS. MAUDE L. SMITH

Mr. MORTON. Mr. President, I ask unanimous consent to revert to Calendar No. 2531, House bill 5584.

The PRESIDING OFFICER. The bill will be read by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H. R. 5584) for the relief of Mrs. Maude L. Smith.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

Mr. MAGNUSON. Mr. President, for the purpose of the record, let me say that I appreciate the consideration of both committees in this case. This woman's small child was killed by a Post Office truck, during the time when there was a hiatus or a vacancy in the city of Seattle in the office of postmaster. The committee thought there might have been some laches on the part of the woman herself, but both postmasters have assured me that there was no laches at all. All the information was before the Judiciary Committee prior to the reporting of the bill. This woman lost her small child. She is quite distraught; and I think what is proposed is the minimum we should do for Mrs. Smith in this case.

Mr. BARRETT. Mr. President, on the basis of the Senator's explanation, we will withdraw the objection.

The PRESIDING OFFICER. The bill is open to amendment. If there be no amendment to be proposed, the question is on the third reading and passage of the bill.

The bill was ordered to a third reading, read the third time, and passed.

PROHIBITION OF USE OF UNTESTED ADDITIVES IN FOOD—BILL PASSED OVER

Mr. TALMADGE. Mr. President—

The PRESIDING OFFICER. The attention of the Chair is called by the Parliamentarian to the fact that there is one more bill at the foot of the calendar, which must be disposed of, namely, Calendar 2487, House bill 13254, which will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

Mr. CLARK. Mr. President, it is my understanding that the Senator from Colorado [Mr. CARROLL] indicated that

he had been asked to object to the bill and to ask that it be passed over, because of the fact that it was objectionable to the junior Senator from Wyoming [Mr. O'MAHONEY], who cannot be present. Accordingly, I must ask that the bill be passed over.

The PRESIDING OFFICER. The bill will be passed over.

DR. HERBERT H. SCHAFER AND HIS WIFE

Mr. TALMADGE. Mr. President, I ask unanimous consent for the present consideration of Calendar No. 2462, Senate bill 4109.

The PRESIDING OFFICER. The bill will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (S. 4109) for the relief of Dr. Herbert H. Schafer and his wife, Irma Niemeyer Schafer.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

Mr. MORTON. I object.

Mr. TALMADGE. Mr. President, will the Senator withhold his objection in order that I may offer an explanation of the bill?

Mr. MORTON. Certainly.

Mr. TALMADGE. This bill was introduced in the Senate by me, and a companion bill was introduced in the House by Representative PAUL BROWN of Georgia, to admit Dr. and Mrs. Schafer to permanent residence in the United States. Its purpose is to prevent the disruption of a vital program of advanced research on diseases of the heart presently being conducted at the Eugene Talmadge Memorial Hospital at Augusta.

Dr. Schafer, a native of Germany and a citizen of France, is director of the Electrocardiographic Laboratory of the Eugene Talmadge Memorial Hospital. That hospital is a State-supported institution operated by the State of Georgia in connection with the Medical College of Georgia for the twofold purpose of providing medical care for indigent Georgians and conducting advanced research, particularly in the fields of cancer and heart disease.

Dr. Schafer presently is engaged in invaluable work in an extensive research project at the Talmadge Hospital which has as its objective the perfecting of surgical techniques for the cure of congenital and rheumatic heart disease. Dr. Schafer's skills in the examination of the heart are considered by hospital authorities to be irreplaceable and his departure would be a great blow not only to Georgia but also to the entire medical profession.

With the assistance of Senator RUSSELL, Congressman BROWN and myself, Dr. Schafer—who is in this country on an exchange-visitor status—sought a waiver of the 2-year foreign residence requirement under Public Law 555. But, because he is not engaged in any research project financed by Federal funds, the United States Public Health Service declined to recommend a waiver for him. And, that being the case, the Department of State and the Immigration and

Naturalization Service had no alternative under the law but also to decline a recommendation.

The Public Health Service did not minimize the importance of Dr. Schafer's work but took the position that it cannot recommend waivers for physicians not directly engaged in Public Health Service projects or research.

The Committee on the Judiciary, recognizing the extenuating circumstances of this case, unanimously recommended passage of S. 4109. However, because waiver had been declined under Public Law 555, an objection was interposed when the measure was considered on Calendar Call yesterday.

It is apparent, Mr. President, that if allowed to continue in his present capacity, Dr. Schafer will be in a position to make a significant contribution to the advancement of medical science.

Unless this bill is passed at this session, Dr. Schafer and his wife will be forced to depart the country and the research project in which he is engaged will be interrupted, if not terminated.

I believe this Senate will agree that it is the national interest that Dr. Schafer and his wife be admitted to permanent residence for the purpose of obtaining citizenship and, on behalf of my colleague and myself, I sincerely hope the Senate will enact this measure.

I sincerely hope that the Senator from Kentucky will withdraw his objection.

Mr. MORTON. Mr. President, do I correctly understand that Dr. Schafer came here on an exchange basis?

Mr. TALMADGE. The Senator is correct.

Mr. MORTON. My objection, of course, is not to Dr. Schafer, whom I do not know.

Mr. TALMADGE. I understand.

Mr. MORTON. I understand about the great work he is doing.

I have a very strong feeling that people who are brought here at the taxpayers' expense in connection with exchange programs should go back to their own countries. That is the purpose of the program.

Mr. TALMADGE. I point out to the Senator, however, that if he had been employed by the Federal Government instead of the State government, the Federal Government would gladly have recommended that he be allowed to remain.

Mr. MORTON. In view of the great work which the Senator assures me the doctor is doing, and in view of the unusual circumstances of the case, I withdraw my objection.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the bill was considered, ordered to be engrossed for a third reading, read the third time, and passed, as follows:

Be it enacted, etc., That, for the purposes of the Immigration and Nationality Act, Dr. Herbert H. Schafer and his wife, Irma Niemeyer Schafer shall be held and considered to have been lawfully admitted to the United States for permanent residence as of the date of the enactment of this act upon payment of the required visa fees. Upon the granting of permanent residence

to such aliens as provided for in this act, the Secretary of State shall instruct the proper quota-control officer to deduct the required numbers from the appropriate quota or quotas for the first year that such quota or quotas are available.

Mr. TALMADGE. Mr. President, I ask unanimous consent to have printed in the RECORD a letter dated August 18, 1958, from Herbert H. Schafer, the beneficiary under the bill, to Hon. PAUL BROWN, a Member of Congress from the State of Georgia.

There being no objection, the letter was ordered to be printed in the RECORD, as follows:

AUGUST 18, 1958.

HON. PAUL BROWN,
Congress of the United States,
House of Representatives,
Washington, D. C.

DEAR CONGRESSMAN BROWN: Thank you for your letter of August 14, 1958, which contained several discouraging enclosures; I received it this morning.

As Senator TALMADGE has informed me by telegram that the Senate Judiciary Committee has favorably reported his bill for my wife's and my relief and Senator TALMADGE expressed hope that the bill will be passed in the Senate and sent to the House this week, I should like to submit some information which the House Judiciary Committee might consider as a mitigating circumstance in my particular case. I thought it important to write you immediately just in case they did meet on private immigration bills this session.

The law states that aliens entering as exchange visitors prior to June 4, 1956, or "who departed as exchange visitors prior to that date will not be subject to the restrictions on immigration provided in Public Law 555 unless they subsequently acquire this status." We could easily have left the country during this "period of grace" and reentered with an immigration visa.

When I entered the United States as an exchange visitor on April 22, 1954, there were no immigration restrictions on such aliens; i. e., I did not fall under this law originally. The reason that I did not make an effort to escape jurisdiction by leaving the United States at that time is as follows: The university was in full teaching session and I was urged not to leave during this critical time. Neither the university nor, of course, myself, realized the extreme likelihood that the waiver request would not be granted. The university officials promised every effort in my behalf—which they have made—and all of us believed that either by the waiver provision or as a last resort by private legislation we could probably expect favorable action. I sincerely hope that the error of judgment in not protecting myself against the restrictions of Public Law 555—which error was made in good faith and out of sense of responsibility to the university—will not end my hopes to have my status changed.

Please accept my gratitude for all your efforts.

Sincerely yours,
HERBERT H. SCHAFER, M. D.

MARKUS H. TEITEL

Mr. JAVITS. Mr. President, I ask unanimous consent for the present consideration of Calendar 2066, House bill 6595.

The PRESIDING OFFICER. The bill will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H. R. 6595) for the relief of Markus H. Teitel.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the bill was considered, ordered to a third reading, read the third time, and passed.

The PRESIDING OFFICER. The Chair lays before the Senate the unfinished business.

MESSAGE FROM THE HOUSE—ENROLLED BILLS AND JOINT RESOLUTIONS SIGNED

A message from the House of Representatives, by Mr. Bartlett, one of its reading clerks, announced that the Speaker had affixed his signature to the following enrolled bills and joint resolutions, and they were signed by the Vice President:

S. 765. An act to increase the authorization for the appropriation of funds to complete the International Peace Garden, N. Dak.;

S. 1542. An act for the relief of Lori Blagi;

S. 2043. An act for the relief of Genoveffa Miglozzi;

S. 2517. An act to amend sections 2275 and 2276 of the Revised Statutes with respect to certain lands granted to States and Territories for public purposes;

S. 2530. An act to designate the beneficiary of the equitable title to land purchased by the United States and added to the Rocky Boy's Indian Reservation, Mont.;

S. 2592. An act to amend the law relating to the execution of contracts with Indian tribes;

S. 2594. An act to transfer certain property and functions of the Housing and Home Finance Administrator to the Secretary of the Interior, and for other purposes;

S. 2850. An act for the relief of Maria Pontillo;

S. 2888. An act to provide for registration, reporting, and disclosure of employee welfare and pension benefit plans;

S. 2922. An act to authorize per capita payments to members of the Red Lake Band of Chippewa Indians from the proceeds of the sale of timber and lumber on the Red Lake Reservation, and for other purposes;

S. 3139. An act to repeal the act of July 2, 1956, concerning the conveyance of certain property of the United States to the village of Carey, Ohio;

S. 3203. An act relating to minerals on the Wind River Indian Reservation in Wyoming, and for other purposes;

S. 3534. An act to authorize the Secretary of the Army to convey approximately 181 acres of land at Fort Crowder Military Reservation to the city of Neosho, Mo.;

S. 3564. An act to accord coverage under the Civil Service Retirement Act to certain temporary rural carriers;

S. 3572. An act to authorize land exchanges for purposes of the George Washington Memorial Parkway in Montgomery County, Md., and for other purposes;

S. 3676. An act for the relief of Maria Michela Leo Di Gioia;

S. 3682. An act to authorize the sale or exchange of certain lands of the United States situated in Pima County, Ariz., and for other purposes;

S. 3723. An act to amend Public Law 522, 84th Congress (relating to the conveyance of certain lands to the city of Henderson, Nev.);

S. 3873. An act to amend section 201 of the Federal Property and Administrative Services Act of 1949, as amended, to authorize the interchange of inspection services between executive agencies, and the furnishing of such services by one executive agency to another, without reimbursement or transfer of funds;

Senate - Aug. 23, 1958

21. VIRGIN ISLANDS. Adopted the conference report on H. R. 12226, to extend until June 30, 1959, the charter of the Virgin Islands Corporation, including new authority to operate salt water distillation facilities and continuation of authority for sugar production. p. 17600
22. FRUITS. Sen. Langer inserted an article on a proposed chokecherry preserve industry in N. D. pp. 17752-3

SENATE - August 23

23. MUTUAL SECURITY APPROPRIATION BILL, 1959. Both Houses received and agreed to the conference report on this bill, H. R. 13192 (H. Rept. 2704). The Senate had passed the bill earlier as reported by the Appropriations Committee. pp. 17787-88, 17826-48, 17850-62, 17955-6, 17974-8, 17991-2, 1897-98 This bill will now be sent to the President.
24. INDEPENDENT OFFICES APPROPRIATION BILL, 1959. Passed with amendments this bill, H. R. 13856. (pp. 17865-76) Rejected, 30 to 45, an amendment by Sen. Williams, for himself and several others, which would have requested the President to review expenditures programmed by the Federal agencies during 1959, and to reduce expenditures 2 percent on defense items, and 4 to 10 percent on expenditures of other agencies (except for certain fixed cost items), and to report on actions taken on such a review to be included in the 1960 budget. (pp. 17868-74) The House concurred in the Senate amendments with an amendment of its own. (p. 17965) The Senate then concurred in the House amendment. (pp. 17994-7) This bill will now be sent to the President.

Received from the President a supplemental appropriation request for the Departments of Labor and Treasury (S. Doc. 119). p. 17758

25. FORESTRY. Passed without amendment H. R. 12281, to authorize the Secretary of Interior to exchange lands to provide for an administrative site in the El Portal area of the Yosemite National Park, including the exchange of National Forest land. (p. 17790) This bill will now be sent to the President.
- Sen. Morse inserted a series of resolutions adopted by the Ore. State Labor Council relating to forestry, timber, forest disease, water power, etc. pp. 17776-8

26. BUTTER; CHEESE. Agreed to the House amendments to S. 2006, to amend the Internal Revenue Code of 1954 so as to relieve the Surgeon General of the Army and Navy from sitting with the Secretary of Agriculture on appeals boards to decide appeals from the decision of the Secretary of the Treasury on cases involving deleterious substances in butter or oleomargarine or in any substance in the manufacture of so-called filled cheese. (pp. 17786-7) This bill will now be sent to the President.

27. SCHOOL LUNCHES. Agreed to the House amendment to S. 1764, to authorize payment of the cost of free lunches for needy children in the D. C. public schools. (p. 17787) This bill will now be sent to the President.

28. FOOD ADDITIVES. Passed with amendments H. R. 13254, to prohibit the use of food additives until after adequate tests of their safety have been determined. Agreed to an amendment by Sen. Williams to exempt from the bill those products regulated under the Poultry Products Inspection Act. The House concurred in the Senate amendment to the bill. (pp. 17791-2, 17938) This bill will now be sent to the President.

elimination of the Senate limitation of 300 rural redevelopment counties, of the appointment of local redevelopment committees, and of the specific employment of private firms for technical assistance; and (e) minor changes in the urban renewal part of the program."

13. FARM PROGRAM. Sen. Proxmire stated that the April 1 reduction in dairy price supports cost Wis. dairymen \$8 $\frac{1}{2}$ million in the past 4 months, and that at the same time consumers had not benefited, and alleged that the Administration's policies were aiding only the middleman. He inserted a table showing the increase in USDA expenditures since 1953, and quoted from a 1952 speech by the President as a basis for contending that the Secretary was following a contrary policy. pp. 17534-6

Sen. Martin, Iowa, spoke on "Fifty Facts For Farmers," citing various statistics and information to show that trends in agriculture were favorable. pp. 17614-6

14. EDUCATION. Agreed, 66 to 15, to the conference report on H. R. 13247, the national defense education bill. pp. 17577-87

Sen. Neuberger inserted an article on the national defense education bill, H. R. 13247. p. 17753

15. PUBLIC DEBT. Passed as reported, 57 to 20, H. R. 13580, to increase the public debt limit to \$288 billion through fiscal year 1959, and \$283 billion thereafter. pp. 17629-30, 17725, 17729-49, 17753-4

16. PERSONNEL. Concurred in the House amendments to S. 1903, to provide that Presidential appointees who serve specific terms of more than 2 years overseas shall be entitled to travel expenses, the same as other Federal employees, when they return to their place of residence at the end of their tour of duty. p. 17590

Sen. Allott commended Federal employees who "under handicaps of more work with fewer people, are doing so well in the field of public service," and cited the Federal Housing Administration office in Colo. as an example. p. 17540

17. FOREIGN AID. Senate began debate on H. R. 13192, the mutual security appropriation bill for 1959. The committee amendments were adopted. pp. 17747-50

Sen. Watkins submitted an amendment to be proposed to H.R. 13192, the mutual security appropriation bill for 1959, to add \$2.5 million to the bill (and allow the President to use such funds to alleviate economic hardships overseas caused by the application of the application of the escape clause provision of the Trade Agreements Act. p. 17515

18. SURPLUS COMMODITIES; FOREIGN TRADE. Sens. Schoeppel urged enactment of legislation to extend Public Law 480 so as to aid in sales of surplus farm commodities. pp. 17529-30

19. APPROPRIATIONS. The Appropriations Committee reported with amendments H. R. 13856, the independent offices appropriation bill for 1959 (S. Rept. 2495). p. 17754

Sens. Bridges and Williams submitted an amendment to be proposed to H. R. 13856, the independent offices appropriation bill for 1959, to request the President to reduce expenditures 2% on defense items, and 4 to 10% on other appropriations (except for fixed cost items such as interest, pensions, Federal-State cooperative benefits, or veterans compensation), with a report on actions taken on such review to be included in the 1960 budget. p. 17754

20. CONTRACTS. Passed as reported H.R. 11749, to extend the Renegotiation Act of 1951 for 6 months. Senate conferees were appointed. pp. 17558, 17596-9

"Edward Arthur Patterson Lake" was considered, ordered to be engrossed for a third reading, read the third time, and passed, as follows:

Resolved by the Senate and House of Representatives of the United States of America in Congress assembled, That the lake to be formed by the waters impounded by the Dickinson Dam in the State of North Dakota shall hereafter be known as "Edward Arthur Patterson Lake," and any law, regulation, document or record of the United States in which such lake is designated or referred to shall be held to refer to such lake under and by the name of "Edward Arthur Patterson Lake."

BILL PASSED OVER

The bill (H. R. 13836) making appropriations for sundry executive bureaus, boards, commissions, corporations, agencies, and offices for the fiscal year ending June 30, 1959, and for other purposes, was announced as next in order.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

Mr. CLARK. Mr. President, that is an appropriation bill, and is not properly calendar business. It should be passed over.

The PRESIDING OFFICER. The bill will be passed over.

PROHIBITION OF USE OF UNTESTED ADDITIVES IN FOOD

The PRESIDING OFFICER. Calendar No. 2487, House bill 13254, was passed to the foot of the calendar. The bill will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Mr. HILL. Mr. President, I ask unanimous consent to have printed in the RECORD at this point a statement which I have prepared on the bill.

There being no objection, the statement was ordered to be printed in the RECORD, as follows:

This bill, which is the result of some 6 years of very intensive hearings held by the House Committee on Interstate and Foreign Commerce, was reported unanimously by that committee to the House, passed the House without dissent and has been unanimously reported by the Committee on Labor and Public Welfare.

The bill has as its objective the correction of two deficiencies in the existing laws under which we undertake to assure the safety of the foods sold to the people of the United States.

In the first place, this legislation would require the processor of foodstuffs who proposes to add to the food any new chemical additive to first prove that the proposed addition will be safe. Under present law the burden of proving any particular additive poisonous or deleterious to humans lies with the Food and Drug Administration. Sometimes a chemical may be added to foodstuffs and used for a considerable period of time before anyone begins to suspect that it may be having ill effects. When and if suspicion has been aroused, more time passes before the Food and Drug Administration can schedule it for investigation.

The scientists of our Food and Drug Administration then undertake investigatory procedures involving testing the chemical additives on small animals. This may take 2 years or even longer. In the meantime, millions of people may be eating the foodstuffs containing the perhaps seriously deleterious additive. An overwhelming percentage of America's food processors of course have voluntarily undertaken to thoroughly test any additives before using them. This bill would require that all processors do so and that no new additives be used without their safety having first been established. The burden of proof is placed where it belongs: Not on the Government, but on the concern which intends to add the chemical to our food.

The second change in existing law would permit American industry to promote new technological developments in food handling calculated to make foods more tasteful and appetizing, to enable them to be kept longer, or to otherwise improve them, through the use of additives now proscribed under a blanket provision of existing law. This legislation, which has the approval of the Food and Drug Administration, would permit the use of additives at safe levels in order to advance our food technology.

I have said that the bill before us passed the House unanimously. I have also pointed out that it has the support of the Food and Drug Administration, which is charged by law with responsibility for protecting the public's health with respect to the foods it eats. I am happy, Mr. President, to be able to also announce that our records indicate that this measure now has the overwhelming support of the major industrial and business concerns which would be affected by it. Its prompt passage is urged not only by the Administration and the committee but by such business groups as:

"National Cannery Association; National Dairy Products Corp., Kraft Foods Division; Grocery Manufacturers of America; Millers National Federation; American Bakers Association; Manufacturing Chemists Association; and the Dairy Industry Committee, speaking for: the American Butter Institute; the American Dairy Milk Institute; the Evaporated Milk Association; the International Association of Ice Cream Manufacturers; the Milk Industry Foundation; the National Cheese Institute; and the National Creameries Association.

The bill will further strengthen the administration of the Pure Food and Drug Act and the protection afforded the American people by that act.

Mr. President, I note the presence of the distinguished senior Senator from Montana, Mr. MURRAY. He is a former chairman of the Senate Committee on Labor and Public Welfare and is always greatly interested in the strengthening of the Pure Food and Drug Act. We owe much to him and his able and devoted leadership.

Questions were raised concerning the interpretation of two words in the bill. The questions were taken up with the Department of Health, Education, and Welfare. Following is a letter from the Department giving its interpretation of those words:

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
Washington, August 20, 1958.

HON. LISTER HILL,
Chairman, Committee on Labor, and
Public Welfare, United States Senate,
Washington, D. C.

DEAR MR. CHAIRMAN: Two questions have arisen about the correct interpretation and the legislative intent of section 2 of H. R. 13254, referred to as the "Food Additives Amendment of 1958." Those questions, and the viewpoints of this Department and of the Food and Drug Administration, are as follows:

1. Does the word "substance," as used in that section, include a food or food component consisting of two or more ingredients? Our interpretation is in the affirmative.

2. Do the words "common use," as used in that section, include a wide use of such a substance by many consumers, even though such a substance may have been used by only a single manufacturer of food or food components? Again our answer is in the affirmative.

We would greatly appreciate it if you would place this letter in the CONGRESSIONAL RECORD in connection with the presentation of the bill for Senate consideration.

Sincerely yours,

ELLIOTT L. RICHARDSON,
Assistant Secretary.

I would add that the term "otherwise affecting the characteristics of any food" refers to an effect not generally recognized as safe among experts qualified by scientific training and experience to evaluate the safety of food additives; but innocuous effects of packaging, such as protection from dirt, retarding moisture loss, preserving shape, providing convenience in use, handling and storage, and the like, would not be covered.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Public Welfare with amendments, on page 15, after line 5, to insert a new section, as follows:

SEC. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be \$20,000.

And after line 7, to insert a new section, as follows:

SEC. 9. Section 208 (g) of the Public Health Service Act, as amended (42 U. S. C. 210 (g)), is amended by striking out the phrase "in the professional and scientific service" and inserting in lieu thereof the phrase "in the professional, scientific, and executive service" and by striking out the phrase "of specially qualified scientific or professional personnel" and inserting in lieu thereof "of specially qualified scientific, professional, and administrative personnel."

Mr. HILL. Mr. President, I ask that the committee amendments be agreed to en bloc.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. WILLIAMS. Mr. President, I offer the amendments which I send to the desk and ask to have stated.

The PRESIDING OFFICER. The amendments offered by the Senator from Delaware will be stated.

The LEGISLATIVE CLERK. On page 2, line 21, after the word "Act," it is proposed to insert the following: "the Poultry Products Inspection Act (21 U. S. C. 451 and the following)."

On page 15, line 3, after the words "pursuant to," it is proposed to insert the following: "the Poultry Products Inspection Act (21 U. S. C. 451 and the following), or."

Mr. HILL. Mr. President, let me say to the distinguished Senator from Delaware that these are very fine amendments. The Department of Agriculture favors the amendments. The Department of Health, Education, and Welfare

has no objection to them. I hope the amendments may be agreed to.

The PRESIDING OFFICER. The question is on agreeing to the amendments offered by the Senator from Delaware.

The amendments were agreed to.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time, and passed.

Mr. WILLIAMS. Mr. President, I ask unanimous consent to have printed in the RECORD at this point a brief statement which I have prepared in connection with my amendment.

There being no objection, the statement was ordered to be printed in the RECORD, as follows:

STATEMENT BY SENATOR WILLIAMS IN CONNECTION WITH AMENDMENT TO H. R. 13254, AS REPORTED BY THE SENATE COMMITTEE ON LABOR AND PUBLIC WELFARE WITH AMENDMENTS

The bill as reported by the Committee on Labor and Public Welfare, as indicated by the provisions of section 2 and section 7 relating to the Meat Inspection Act, is not intended, as indicated by the committee report on page 9, to affect the jurisdiction of the Department of Agriculture under the Meat Inspection Act. Apparently through an oversight similar reference is not made in the bill to the Poultry Products Inspection Act, which was enacted during the last session of this Congress, dealing with a mandatory inspection program for poultry. This omission of reference to this act may have been due to the language of section 18 of the Poultry Products Inspection Act which indicates clearly the congressional intent with respect to the scope and nature of the jurisdiction of the Secretary of Agriculture under that act. However, in order to make it abundantly clear that, as in the case of the Meat Inspection Act, it is not the intention of the Congress in passing this bill to in any way affect the scope or nature of the jurisdiction of the Department of Agriculture under the Poultry Products Inspection Act, I am offering an amendment which will include in the bill references to the Poultry Products Inspection Act similar to those made to the Meat Inspection Act.

ORDER OF BUSINESS

The PRESIDING OFFICER. That concludes the calendar.

Mr. MORSE. Mr. President, will the Chair advise the Senator from Oregon where the call of the calendar was started?

The PRESIDING OFFICER. The call started at the beginning, but all the order numbers up to 1684 were objected to; also order numbers 1990 to 2479 were objected to, and were passed over.

The call was resumed with order No. 2487, a bill which was passed to the foot of the calendar when it was called, and which has just now been passed.

Mr. MORSE. Was any action taken on Calendar 2091, House bill 6995?

The PRESIDING OFFICER. It was passed over with a group of bills en bloc.

Mr. MORSE. What action was taken with regard to Calendar 2427, Senate bill 2020?

The PRESIDING OFFICER. It was passed over with a group of bills en bloc.

AMENDMENT OF RAILROAD RETIREMENT ACT AND RAILROAD UNEMPLOYMENT INSURANCE ACT

Mr. MORSE. Mr. President, would it be out of order for me to make a brief statement in connection with Calendar No. 2427, Senate bill 2020?

The PRESIDING OFFICER. The Senator from Oregon has the floor.

Mr. MORSE. Mr. President, I invite the attention of Senators to Calendar No. 2427, Senate bill 2020, a bill to amend the Railroad Retirement Act of 1937 and the Railroad Unemployment Insurance Act. I hope it can be considered some time before adjournment. I should like to tell the Senate why, and I should like to have the attention of the Senator from Kentucky [Mr. COOPER], who is familiar with the bill, as is the Senator from Alabama [Mr. HILL], who is also a member of our committee, and the Senator from Michigan [Mr. McNAMARA]. They are the only members of the Committee on Labor and Public Welfare whom I see present in the chamber. I call upon them to check the statement I am about to make to the Senate.

This is a technical bill. It is a bill which seeks to bring to an end the jurisdictional conflict between the Railroad Retirement Board and the Social Security Board in connection with so-called freeze disability cases, disability cases where the person disabled worked for a time for a railroad, then for a time did not work for the railroad, and became disabled. Who will have jurisdiction? Will the jurisdiction be had by the Railroad Retirement Board or by the Social Security Board? The interesting thing is that the pattern of setting these cases by way of disability allowance is the same whether the cases are handled by the Railroad Retirement Board or by the Social Security Board. We all know, however, that in governmental departments there develops a desire to hold on to whatever any given agency thinks comes within its jurisdiction, and not yield jurisdiction to another agency in what it thinks is an encroachment in the field of jurisdiction. That is the problem which confronted us in the Committee on Labor and Public Welfare and in our subcommittee.

Therefore we said to both agencies: "Get your heads together. Stop bothering us with this kind of administrative detail." There is no reason in the world why these two agencies should not sit down and decide how they are going to solve this little jurisdictional conflict. The result was that we received a letter some time later which advised us that they had gotten their heads together. We took their agreement, and it is now in the form of S. 2020.

I wish to be completely accurate, and therefore state that subsequent to the submission of the joint agreement between these two agencies, someone in the Social Security Administration had a second thought, and wanted a further modification made. We took the position it was too late. We said they had worked out a fair agreement in the first place and we had accepted it, and we

were going to stand on that acceptance.

Mr. President, we should not go into another year without passing this technical bill. We should pass it now. If it does not work out to the satisfaction of both agencies, they can come back to us. However, I will tell Senators what the result will be if Congress makes this administrative decision based upon the joint understanding which the agencies have reached. It will mean that both agencies will adjust to it and we will hear nothing further about it. If we keep the bill on the calendar, and adjourn with it on the calendar, we will keep the fires of dispute and disagreement between these two great agencies burning. The time has come to squelch them.

I hope at some time today we will bring up S. 2020, for not more than a minute's debate, and get it behind us, and get it to the House and get it voted on, so that the Committee on Labor and Public Welfare, come January, can devote its time to more important matters than to have these agencies come before the committee and wash their jurisdictional linen in front of us. That is my plea. I can say no more. I ask my chairman, the Senator from Alabama [Mr. HILL] and the Senator from Kentucky [Mr. COOPER] and other members of the committee if I have said anything that is not in accord with the facts.

Mr. JOHNSON of Texas. Mr. President, if we can pass the bill in a minute, I ask unanimous consent that we proceed to its consideration.

Mr. MORSE. I have made my case.

The PRESIDING OFFICER. The bill will be stated by title for the information of the Senate.

The CHIEF CLERK. A bill (S. 2020) to amend the Railroad Retirement Act of 1937 and the Railroad Unemployment Insurance Act.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Labor and Public Welfare with amendments on page 2, line 1, after the word "subsection", to strike out "and all purposes of title II of the Social Security Act"; in line 18, after the word "year", to strike out "Provided, That no such period of disability shall be deemed to have begun if the employee died before July 1, 1955."; in line 21, after the word "Provided", to strike out "further"; on page 3, line 3, after the word "July", to strike out "1957" and insert "1958", after the amendment just above stated, to strike out "And provided" and insert "Provided further"; in line 11, after the word "act", to strike out "For purposes of section 5 (k) (2) of this act, any determination by the Board of a period of disability for an employee shall be considered a determination of such a period for such employee by the Secretary of Health, Education, and Welfare under section 216 (i) of the Social Security Act, and for such purposes section 222 (b) of the Social Security Act shall not apply with respect to any individual whose period of disability is determined

passed, and a motion to reconsider was laid on the table.

A similar House bill was laid on the table.

FOOD ADDITIVES

Mr. HARRIS. Mr. Speaker, I ask unanimous consent to take from the Speaker's table the bill (H. R. 13254) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety, with Senate amendments, and concur in the Senate amendments.

The Clerk read the title of the bill.

The Clerk read the Senate amendments, as follows:

Page 2, line 21, after "act" insert ", the Poultry Products Inspection Act (21 U. S. C. 451 and the following)."

Page 15, line 3, after "to" insert "the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or."

Page 15, after line 5, insert:

"Sec. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be \$20,000."

The SPEAKER. Is there objection to the request of the gentleman from Arkansas [Mr. HARRIS]?

Mr. CURTIS of Missouri. Mr. Speaker, reserving the right to object, will the gentleman make a short explanation of the bill and the amendments?

Mr. HARRIS. This is referred to as the food additives bill, which passed the House a few days ago.

Mr. CURTIS of Missouri. The amendments are germane to the bill?

Mr. HARRIS. They are.

Mr. CURTIS of Missouri. I withdraw my reservation of objection, Mr. Speaker.

The SPEAKER. Is there objection to the request of the gentleman from Arkansas [Mr. HARRIS]?

There was no objection.

The Senate amendments were concurred in.

A motion to reconsider was laid on the table.

Mr. WILLIAMS of Mississippi asked and was given permission to revise and extend his remarks at this point in the Record.)

Mr. WILLIAMS of Mississippi. Mr. Speaker, H. R. 13254 is the so-called food additives bill which passed the House several weeks ago.

The Senate accepted the House bill in its entirety, and added several amendments, the effect of which is as follows:

First. Language added on page 2, line 21, and page 15, line 3, would exempt from the scope of the legislation substances already approved under the provisions of the Poultry Products Inspection Act. These exemptions would be in addition to those already contained in the bill as passed by the House for substances approved under the provisions of the Federal Food, Drug, and Cosmetic Act and the Meat Inspection Act of March 4, 1907. This amendment is requested by the poultry industry and concurred in by the Departments of Agriculture and Health, Education, and Welfare.

Second. A new section 8 added by the Senate would increase the annual rate of compensation of the Commissioner of Food and Drugs from \$17,500 to \$20,000. The Department of Health, Education, and Welfare has suggested that in light of the scope and complexity of the program administered by the Commissioner of Food and Drugs, his salary should be increased as provided in this amendment.

Third. A new section 9 added by the Senate would amend section 208 (g) of the Public Health Service Act, as amended, to authorize the employment of key executive and administrative personnel in the Public Health Service, particularly in the National Institutes of Health, at a higher rate of compensation.

Section 208 (g) now authorizes the Secretary of Health, Education, and Welfare to establish and fix the compensation, within the Public Health Service, for not more than 85 positions—of which not less than 73 shall be for the National Institutes of Health—in the professional and scientific service, to effectuate the research and development activities which require the services of specially qualified scientific or professional personnel. The rate of compensation for these positions is to be not less than \$12,500 per annum and not more than \$19,000 per annum, and these positions are subject to the approval of the Civil Service Commission. The Senate amendment would add "executive service" and "administrative personnel" to the "professional and scientific service" and the "specially qualified scientific or professional personnel."

This legislation, if enacted, would enable the Secretary of Health, Education, and Welfare to provide adequate compensation for key executive and administrative personnel in the National Institutes of Health such as, for example, the Executive Officer of the National Institutes of Health, the executive officers of several of the larger institutes, and the officers in charge of research planning and scientific information. The amendment would not increase the total number of positions now authorized pursuant to section 208 (g) and would not modify the maximum salary limitations under that section.

This amendment has the approval of the Department of Health, Education, and Welfare.

Since the food additive bill, H. R. 13254, passed the House, I have received an inquiry as to how this legislation affects the packaging industry. Of course, packaging ordinarily is not intended or reasonably expected to become a part of food and therefore would not come under the bill. The term "otherwise affecting the characteristics of any food" refers to an effect not generally recognized as safe among experts qualified by scientific training and experience to evaluate the safety of food additives; but innocuous effects of packaging, such as protection from dirt, retarding moisture loss, preserving shape, providing convenience in use, handling, and storage, and the like, would not be covered.

AMENDING HOUSE RESOLUTION 149, 85TH CONGRESS

Mr. SMITH of Virginia. Mr. Speaker, I call up the resolution, House Resolution 619, by direction of the Committee on Rules, and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved, That House resolution 149, 85th Congress, as amended, is amended by inserting after "North American Continent," the following: "and elsewhere in connection with any study or investigation of ocean steamship conferences and the dual rate system."

With the following committee amendment:

Page 1, strike out lines 1, 2, 3, 4, and down to and including the word "system" in line 5, and insert "That H. Res. 149, 85th Congress, as amended, is further amended by striking out the 1st sentence in paragraph 2 thereof and inserting in lieu thereof the following: 'For such purposes the said committee or any subcommittee thereof as authorized by the chairman is hereby authorized to sit and act during the present Congress at such times and places within the United States, its Territories and possessions, within the North American Continent, or elsewhere when in connection with any study or investigation of ocean steamship conferences and the dual rate system, whether the House has recessed, or has adjourned, to hold such hearings, and to require by subpoena or otherwise the attendance and testimony of such witnesses and the production of such books, records, correspondence, memorandums, papers, and documents, as it deems necessary: *Provided, however*, That in no event shall the chairman designate more than 5 committee members and 2 staff members to proceed outside the United States on any one study or investigation of ocean steamship conferences and the dual rate system.'"

Mr. BROWN of Ohio. Mr. Speaker, will the gentleman yield?

Mr. SMITH of Virginia. I yield to the gentleman from Ohio.

Mr. BROWN of Ohio. Mr. Speaker, I asked for this time in order to inquire if this is not the resolution which would permit the Committee on Merchant Marine and Fisheries to travel abroad and to investigate certain activities in which the committee is interested.

Mr. SMITH of Virginia. I might make a brief explanation of what the resolution is.

Mr. BROWN of Ohio. I wish the gentleman would.

Mr. SMITH of Virginia. Mr. Speaker, as is well known, all legislative committees have the right to investigate matters within their jurisdiction, but only those which have a special resolution may travel outside of the continental United States.

A recent decision of the Supreme Court has caused some trouble among the steamship lines with respect to what is known as dual-rate contracts. It is going to be necessary to have some conferences between officials of various ship-owning corporations, and it is going to be advisable for some members of the Merchant Marine and Fisheries Committee to attend those conferences. If they take place in the United States this resolution will not be necessary, but if they do not, it may be necessary.

"(iv) if there be no such widow, widower, child, or grandchild, to any parent or parents of such employee; or

"(v) if there be no such widow, widower, child, grandchild, or parent, to any brother or sister of such employee; or

"(vi) if there be no such widow, widower, child, grandchild, parent, brother, or sister, to the estate of such employee, a lump sum."

(c) The first sentence of section 5 (h) of such act is amended by striking out "prior to" and inserting in lieu thereof "after."

(d) Section 5 (i) (3) of such act is amended (1) by inserting "and" after the semicolon in subparagraph (i); (2) by striking out all of subparagraph (ii) after "title II of the Social Security Act" and inserting in lieu thereof a period; and (3) by striking out subparagraphs (iii) and (iv).

(e) Section 5 (k) (3) of such act is amended—

(1) by inserting in the first sentence after "service" the following: ", of determinations under section 3 (e) of this act, or section 216 (1) of the Social Security Act, of periods of disability within the meaning of such section 216 (1);";

(2) by inserting in the first sentence after "this section" the following: ", section 3 (e) of this act;"; and

(3) by inserting in the second sentence after "therein" the following: "(except in the case of a determination of disability under section 216 (1) of the Social Security Act."

(f) Section 5 (l) (6) of such act is amended by striking out the parenthetical phrases in the first and second sentences and by inserting at the end thereof the following sentence: "Wages, as defined in this paragraph, shall be credited for the purposes of this section in the manner and to the extent credited for corresponding purposes of title II of the Social Security Act."

(g) Section 5 (l) (7) (ii) of such act is amended by striking out "forty or more quarters of coverage" and inserting in lieu thereof the following: "either will have had forty or more quarters of coverage or would be fully insured under title II of the Social Security Act if his service as an employee after December 31, 1936, were included in the term 'employment' as defined in that act."

(h) Section 5 (l) (8) of such act is amended (1) by striking out "will have had (i)" and inserting in lieu thereof "(i) will have had"; (2) by inserting "either will have had" after "(ii)", and (3) by inserting before the final period a comma and the following: "or would be currently insured under title II of the Social Security Act if his service as an employee after December 31, 1936, were included in the term 'employment' as defined in that act."

(i) Section 5 (l) (9) of such act is amended—

(1) by striking out "quarter in which he will have died" each place it appears in clauses (A) and (B) and by inserting in lieu thereof "employee's closing date";

(2) by striking out the last proviso; and

(3) by inserting after the first sentence the following new sentence: "An employee's 'closing date' shall mean (A) the first day of the first calendar year in which such employee both had attained age 65 and was completely insured; or (B) the first day of the calendar year in which such employee died; or (C) the first day of the calendar year following the year in which such employee died, whichever would produce the highest 'average monthly remuneration' as defined in the preceding sentence. If the amount of the 'average monthly remuneration' as computed under this paragraph is not a multiple of \$1, it shall be rounded to the next lower multiple of \$1."

SEC. 3. Section 10 (b) (4) of the Railroad Retirement Act of 1937 is amended by inserting after the third sentence the follow-

ing new sentence: "For purposes of its administration of this act or the Railroad Unemployment Insurance Act, or both, the Board may hereafter place, without regard to the numerical limitations contained in section 505 of the Classification Act of 1949, as amended, 4 positions in grade GS-16 of the general schedule established by that act, 4 positions in grade GS-17 of such schedule, and 1 position in grade GS-18 of such schedule."

SEC. 4. Section 13 of the Railroad Retirement Act of 1937 is amended (1) by inserting "(a)" after "Sec. 13."; (2) by inserting ", or both" before the final period, and (3) by adding at the end thereof the following new subsection:

"(b) All fines and penalties imposed by a court pursuant to this act shall be paid to the court and be remitted from time to time by order of the judge to the Treasury of the United States to be credited to the Railroad Retirement Account."

SEC. 5. (a) The amendments made by sections 1 (a), 1 (d), 1 (e), and 2 (i) shall be effective with respect to annuities awarded under the Railroad Retirement Act of 1937 on or after the date of the enactment of this act.

(b) The amendments made by sections 2 (g) and 2 (h) shall be effective (1) with respect to deaths occurring on or after the date of the enactment of this act and (2) with respect to any death occurring before such date if none of the survivors of the deceased individual became entitled before such date to monthly benefits, by reason of the individual's death, under title II of the Social Security Act.

(c) The amendments made by section 1 (b) shall be effective with respect to determinations of periods of disability, within the meaning of section 216 (1) of the Social Security Act, made on or after the date of the enactment of this act.

(d) The amendments made by sections 1 (c), 2 (a), and 2 (b) shall be effective with respect to deaths occurring in months after the month in which this act is enacted.

(e) The amendments made by sections 2 (c), 2 (d), and 2 (f) shall be effective with respect to annuities accruing for months after the month in which this act is enacted.

(f) The amendments made by sections 2 (e) and 3 shall be effective on the date of the enactment of this act.

(g) The amendment made by clause (3) of section 4 shall be effective with respect to offenses committed on or after the date of the enactment of this act; and the other amendments made by section 4 shall be effective with respect to fines and penalties imposed on or after such date.

PART II—AMENDMENTS TO THE RAILROAD UNEMPLOYMENT INSURANCE ACT

SEC. 201. (a) (1) The second proviso in section 1 (k) of the Railroad Unemployment Insurance Act is amended by striking out "second" and inserting in lieu thereof "first", and by striking out "first" and inserting in lieu thereof "second."

(2) The second paragraph of such section 1 (k) is amended by striking out "one dollar" and inserting in lieu thereof "three dollars."

(b) Section 1 (q) of such act is amended by inserting before the period at the end thereof the following: "in the unemployment trust fund."

SEC. 202. Section 4 (a-1) (ii) of the Railroad Unemployment Insurance Act is amended by striking out all that follows "sickness compensation law" and precedes the first proviso and by inserting in lieu thereof the following: "other than this act, or any other social-insurance payments under any law."

SEC. 203. Section 8 (a) of the Railroad Unemployment Insurance Act is amended by inserting before the period at the end thereof a semicolon and the following: "and in de-

termining such balance as of September 30 of any year, the balance to the credit of the railroad unemployment insurance administration fund as of the close of business on such date shall be deemed to be a part of the balance to the credit of such account."

SEC. 204. (a) Section 904 (a) of the Social Security Act is amended by inserting after "the railroad unemployment insurance account" the following: "or the railroad unemployment insurance administration fund."

(b) Section 904 (e) of the Social Security Act is amended by striking out "and the railroad unemployment insurance account" and inserting in lieu thereof the following: "the railroad unemployment insurance account, and the railroad unemployment insurance administration fund."

(c) Section 904 (f) of the Social Security Act is amended by striking out "fund as the Railroad Retirement Board" and all that follows and by inserting in lieu thereof the following: "railroad unemployment insurance account for the payment of benefits, and out of the railroad unemployment insurance administration fund for the payment of administrative expenses, as the Railroad Retirement Board may duly certify, not exceeding the amount standing to the credit of such account or such fund, as the case may be, at the time of such payment."

SEC. 205. (a) Section 11 of the Railroad Unemployment Insurance Act is amended by striking out the first sentence and the first two words of the second sentence, and by inserting in lieu thereof the following: "The Secretary of the Treasury shall maintain in the unemployment trust fund established pursuant to section 904 of the Social Security Act an account to be known as the railroad unemployment insurance administration fund. This unemployment insurance administration fund."

SEC. 206. The second paragraph of section 12 (1) of the Railroad Unemployment Insurance Act is amended by striking out "Classification Act of 1923, except that the Board may fix the salary of a director of unemployment insurance at \$10,000 per annum" and inserting in lieu thereof the following: "Classification Act of 1949, as amended."

SEC. 207. (a) The amendments made by section 201 (a) shall be effective with respect to registration periods in benefit years after the benefit year ending on June 30, 1958.

(b) The amendments made by section 201 shall be effective with respect to days in benefit years after the benefit year ending on June 30, 1958.

(c) The remaining amendments made by this part shall be effective, except as otherwise indicated therein, on the date of the enactment of this act.

PART III—AMENDMENTS TO THE SOCIAL SECURITY ACT

SEC. 201. Section 202 (t) of the Social Security Act is amended by changing the period at the end of paragraph (4) thereof to a comma and inserting thereafter the word "or" and the following:

"(E) the individual on whose employment such benefit is based had been in service covered by the Railroad Retirement Act which was treated as employment covered by this act pursuant to the provisions of section 5 (k) (1) of the Railroad Retirement Act."

SEC. 302. The amendments made by section 301 of this act shall apply with respect to monthly benefits under section 202 of the Social Security Act for months after December 1956, and with respect to lump-sum death payments under such section 202 in the case of deaths occurring after December 1956.

The bill was ordered to be read a third time, was read the third time, and

Public Law 85-929
85th Congress, H. R. 13254
September 6, 1958

AN ACT

72 Stat. 1784.

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to prohibit the use in food of additives which have not been adequately tested to establish their safety.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Food Additives Amendment of 1958".

Food Additives
Amendment of
1958.
52 Stat. 1041.
21 USC 321.
Definitions.

SEC. 2. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended by adding at the end of such section the following new paragraphs:

"(s) The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

"(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U. S. C. 71 and the following).

71 Stat. 441.

"(t) The term 'safe', as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal."

SEC. 3. (a) Clause (2) of section 402 (a), as amended, of such Act is amended to read as follows: "(2) (A) if it bears or contains any added poisonous or added deleterious substance (except a pesticide chemical in or on a raw agricultural commodity and except a food additive) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408 (a), or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity;"

Insanitary
ingredients.
21 USC 342.

21 USC 342.

(b) Section 402 (a), as amended, of such Act is further amended by striking out the period at the end thereof and inserting in lieu thereof a semicolon and the following: "or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409."

21 USC 346.

(c) The first sentence of section 406 (a) of such Act is amended by striking out "clause (2)" wherever it appears in such sentence and inserting in lieu thereof "clause (2) (A)".

21 USC 341
et seq.

SEC. 4. Chapter IV of such Act is amended by adding at the end thereof the following new section:

"FOOD ADDITIVES

"Unsafe Food Additives

"SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 402 (a), unless—

"(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

"(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402 (a).

"Petition To Establish Safety

"(b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

"(2) Such petition shall, in addition to any explanatory or supporting data, contain—

"(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

"(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

"(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

"(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

"(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

"(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, with-

out disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

“(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

“(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

“Action on the Petition

“(c) (1) The Secretary shall—

“(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

“(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

“(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

“(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

“(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

“(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

“(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

“(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

“(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

“(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

“(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

“(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

“(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

“Regulation Issued on Secretary’s Initiative

“(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

“Publication and Effective Date of Orders

“(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

“Objections and Public Hearing

“(f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

“(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

“(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

“Judicial Review

“(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place

of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

"(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

"(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.

"(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

"(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

"Amendment or Repeal of Regulations

"(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

"Exemptions for Investigational Use

"(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

SEC. 5. Section 301 (j) of such Act is amended by inserting "409," 21 USC 331, after "404,"

SEC. 6. (a) Except as provided in subsections (b) and (c) of this section, this Act shall take effect on the date of its enactment. Effective dates.

(b) Except as provided in subsection (c) of this section, section 3 of this Act shall take effect on the one hundred and eightieth day after the date of enactment of this Act. Ante, p. 1784

(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act shall take effect—

Ante, p. 1784

(1) either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such additional

period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

Ante, p. 1785. (2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act becomes effective, whichever date first occurs.

71 Stat. 441.

SEC. 7. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U. S. C. 451 and the following) or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U. S. C. 71 and the following).

Compensation of
Commissioner.

SEC. 8. The annual rate of basic compensation of the Commissioner of Food and Drugs shall be \$20,000.

69 Stat. 407,
70 Stat. 430,
741.

SEC. 9. Section 208 (g) of the Public Health Service Act, as amended (42 U. S. C. 210 (g)), is amended by striking out the phrase "in the professional and scientific service" and inserting in lieu thereof the phrase "in the professional, scientific, and executive service" and by striking out the phrase "of specially qualified scientific or professional personnel" and inserting in lieu thereof "of specially qualified scientific, professional, and administrative personnel".

Approved September 6, 1958.

3540 E

F.B.I.
SEA/TIS
LAW LIBRARY
ROOM 1406 SOUTH
WASHINGTON D.C. 20250